XFYRE
Advanced Defence & Security Technology

Tiller INTERNATIONAL CAPITAL

2021
CORPORATE PROFILE

Information & Business Catalog

Innovation of

IDEAS & EFFICIENCY

in any of our endeavours

XFYRE (M) SDN BHD was conceived with the notion to break grounds and shift the nature of various industries. We believe in the innovation of ideas and efficiency in any of our endeavours.

Our team has experience in various projects ranging from telecommunication, network, power utility, security, forensics, surveillance, cyber-warfare and defence contract. We have assisted many government agencies in the area of threat management, intelligence gathering and research & development.

"Do not go where the path may lead, go instead where there is no path and leave a trail"

- Ralph Waldo Emerson

PHILOSOPHY & METHODOLOGY

To maintain high ethical standards in external and internal relationships. Decisions should be based on facts and objectively considered. Business should be kept in adjustment with the forces at work. People should be judged on the basis of their performance, not on personality, education or personal traits and skills. All business should be administered with a sense of competitive urgency.

VISION & PRINCIPLES

We believe in simplifying experience and providing disruptive pricing to enhance business competitiveness of our clients. Out strong fundamentals pushes innovation and we strongly believe in focusing on the few that are truly important and meaningful to us.

"Do not go where the path may lead, go instead where there is no path and leave a trail" - Ralph Waldo Emerson

PERSISTENCE

We do not say "NO" to our customers. We ensure every project that we undertake, we deliver with sheer excellence. We make sure delivered projects are monitored thoroughly even after completion. We maintain high level communications with our customers to ensure our products and services meet their standards and expectations.

PREPARATION

We expect nothing less from our people. We are industry certified from PMP (Project Management Institute), ITIL (IT Governance and Infrastructure/Service), Six Sigma (Business Process Improvement), Microsoft, Cisco (Networking), VMWARE (Virtual Machines), Citrix, BS7799/ISO 27002 (Security Policy), CIA/CISA (Audit Control and Security) and many other various certification in long standing industry. Our people are equipped, certified and ready to embark on any projects given in relation to our business.

MEDICAL EQUIPMENT
CATALOG

DISPOSABLE GLOVES

1 DISPOSABLE NITRILE GLOVES

Provide protection from unwanted substances or potentially dangerous substances for both the professionals and patients. These gloves are made from high quality 100% nitrile (A synthetic co-polymer – Acrylonitrile-Butadiene) are Latex Free and are suitable for NR Latex- Sensitive Medical Professionals (Type 1 allergic reactions)

- Unique formulation makes the glove soft and flexible for a comfortable fit
- Micro-Textured surface provides non-slip grip when handling instruments
- The dual leached gloves have low chemical residue
- High tensile strength due to its special formulation
- Beaded cuff ensures secured and easy donning

2 DISPOSABLE LATEX GLOVES

Superior price verses performance value and treated them with a proprietary Polymer Coat and Surface treatment to provide you with a pair of gloves free of powder for even more stringent contamination control.

- Unique latex formulation resulting in superior barrier protection with Low Allergenic Protein content
- Proprietary Polymer Coat and Surface treatment for easy donning without any dusting powder.
- Balanced weight versus thickness ratio for optimal performance usage
- Ambidextrous shape provides comfort even during long period of use

3 DISPOSABLE LATEX SURGICAL GLOVE

Latex surgical gloves have been developed specifically with doctors in mind. Incorporating a proprietary latex formulation, we have been able to produce these gloves to give superior barrier protection yet provide comfort and all around dexterity for long hours during surgical operations. The gloves don easily and securely over surgical gowns and with a Micro-Textured surface, users are able to hold their instruments with more confidence. They also meet all regulatory requirements for Biocompatibility testing and Latex Protein Allergy.

- Unique latex formulation resulting in superior barrier protection with Low Allergenic Protein content
- Micro-Textured surface provides non-slip grip when handling instruments
- 300mm glove length provides secured donning at all times during surgical procedures

4 DISPOSABLE PVC / VINYL GLOVE

Vinyl is a synthetic, non-bio-degradable, protein-free material made from polyvinyl chloride (PVC) and plasticizers. Since vinyl gloves are synthetic and non-biodegradable, they have a longer shelf life than latex gloves, which often start to break down over time. Vinyl is also not very form fitting compared to latex or nitrile, giving the wearer limited dexterity and a higher chance that the glove with catch and tear.

- Latex-free
- Have a looser fit
- Are good for short-term, low-risk tasks

HEALTHSOURCE

Medical Grade Nitrile Gloves By XFYRE

A TILLER HEALTH COMPANY

- Protection from unwanted or dangerous substances
- Beaded cuff makes donning easy and helps prevent roll back
- Superior strength with better puncture resistance
- Full textured enhances wet and dry grip
- Thinner gauger improves tactile sensitivity
- Custom design enhances comfort and fit
- Provide an alternative solution for individuals who are allergic to natural rubber latex

Product Detail

Type		Powder-Free, Non-sterile
Material Weight (gsm)		-
Color		Blue, White, Green, Purple, Black
Sizes		X-Small, Small, Medium, Large, X-Large
MOQ		1 ctn
Gross weight per item		3.5-5.5gram
Packing (CTN)	box	100 units
	ctn	Box : 240x120x70 (mm) / 24x12x70 (cm) Carton: 360x250x250 (mm) / *36x25x25 (cm)* 10box / ctn 3.5-5.5 kg
	units/ctn	1000
40 HC Container	ctn	3,200
	units/box	32,000
Manufacture location		Malaysia

International Quality Certificate Awarded : Medical Device, SIRIM, ASTM, EN455, CE, ISO, FDA

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Specification and Performance

Product Type	Nitrile Examination Glove Disposable
Material	Nitrile Butadiene Rubber (NBR)
Design & Feature	Ambidextrous. Beaded Cuff. Finger Textured
Size Available	S, **M,** L, XL
Donning Aid	Chlorinated
Product Classification	FDA 80LYY 880.6250 MOD Class I
Powder Content	Max. 2.0 milligram/glove
Protein Content	N/A
Performance **Standard**	ASTM 0-6319 EN 455-Part 1. 2 and 3
Packing **Style**	Bulk Pack
Shelf Life	Product shall have shelf life of 3 years from the date of manufacture with the above storage condition
Storage Condition	Product shall be stored under 10om condition, avoid sunlight

PHYSICAL DIMENSION - 3 MILS,240 MM / 9"

Size	S	M	L	XL	Thickness(mm)	
Ave width (mm)	95..t4	102 5	108:1:5	114 J:5	Cull	0.040.10.02
Ave weight (gm)	9.0±1.0	9.5±1.0	10.0±1.0	10.5±1.0	Palm	0.070±0.02
Length (mm)	Min 240				Finger	0.080±0.02

PHYSICAL PROPERTIES - ASTM

Parameters	Tensile Strength (MPa)	Elongation at break (%)	Modulus at 500% (MPa)	Tensile Strength (MPa)	Elongation at break (%)	Modulus at 500% (MPa)
Hanser Result	18 - 28	650 - 750	Max 2.8	14 - 18	500 - 650	Max 28
ASTM Requirement (min)	Min 14	Min650%	Max 2.8	Min 14	Min500%	N/A

PHYSICAL PROPERTIES - EN

Parameters	Before Aging		After Aging	
	Force at Break (N)	Elongation at break (%)	Force at Break (N)	Elongation at break (%)
Hanser Result	9.0 - 11.0	N/A	6.0 - 10.0	N/A
ASTM Requirement (min)	Min 9 N	N/A	Min 6 N	N/A

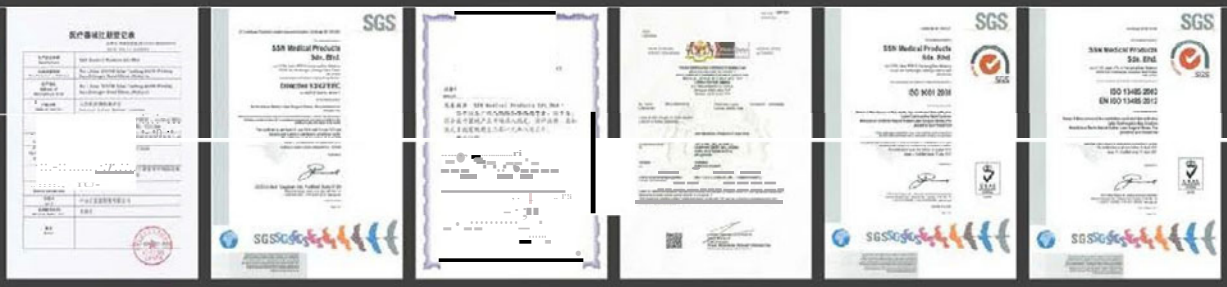
CHEMICAL ANALYSIS

Requirement	Protein Content	Powder Content
	Pre-powdered	Pre-powdered
Hanser Result	N/A	Below 2.0
FDA min requirement	N/A	Max 2.0 milligram/glove

PERFORMANCE

Inspection	Related Defects	Inspection Level	AQL
Watertight Test	Holes	G-1	1.0
Visual Inspection	Major Defects	G-1	2.5
	Minor Defects	G1	4.0
Physical Properties	Tensile Strength and Elongation	S-2	4.0
Physical Dimension	Measurement	S-2	4.0

Certificate



XFYRE
Advanced Defence & Security Technology

PRODUCT STANDARD SPECIFICATIONS, PERFORMANCE & CONFORMANCE
THERACOM NITRILE DISPOSABLE GLOVE

Product	Nitrile Disposable Glove
Type	Powdered & Powder-Free, Non-sterile
Material	100% Synthetic Nitrile Latex
Design & Feature	Ambidextrous, Beaded Cuff, Finger Textured
Colour	Blue, White, Green, Purple, Black
Size Available	Extra-Small, Small, Medium, Large, Extra-Large
Design & Features	Powdered: Ambidextrous, finger textured or palm textured surface, beaded cuff, USP grade absorbable cornstarch Powder-Free: Polymer coated or online single chlorinated, offline double chlorinated, ambidextrous, finger textured or palm textured surface, beaded cuff
Donning Aid	Chlorinated
Powder Content	Max. 2.0 milligram/glove
Protein Content	N/A
Quality Standards	• Conforms to ASTM D6319 and EN455 Standards • Manufactured under QSR (GMP), ISO 9001:2015 and ISO 13485:2016 Quality Management System
Packing Style	100 pcs per box
Shelf Life	Product shall have shelf life of 5 years from the date of manufacture with the above storage condition
Storage Condition	Product shall be stored under room condition, avoid direct sunlight

GENERAL SPECIFICATION

Size	XS	S	M	L	XL
Weight (g)	3.5 ± 0.4	4 ± 0.4	4.5 ± 0.5	5 ± 0.5	5.5 ± 0.6
Net (Kg/Ctn)	3.9	4.4	5	5.5	6.1
Gross (Kg/Ctn)	5.4	5.9	6.5	7	7.6

PHYSICAL DIMENSIONS

Dimensions	Dimensions		
	XFYRE	**ASTM D3578**	**EN 455**
Type	Min 230, Min 240, 300 ± 10	Min 220 (XS, S) Min 230 (M, L, XL)	Min 240
Palm Width (mm)			
XS	76 ± 3	70 ± 10	≤ 80
S	84 ± 3	80 ± 10	80 ± 10
M	94 ± 3	95 ± 10	95 ± 10
L	105 ± 3	110 ± 10	110 ± 10
XL	113 ± 3	120 ± 10	≥ 110
Thickness : Single Wall (mm)			
Finger	Min 0.06	Min 0.05	Min 0.05
Palm	Min 0.06	Min 0.05	Min 0.05

PHYSICAL PROPERTIES

Property	Before Aging	After Aging
Tensile Strength (MPa)	Min 14	Min 14
Elongation at Break (%)	Min 500	Min 400
Force at Break (N)	Min 6	Min 6

DISPOSABLE FACE MASK

1 PROTECTIVE N95

Capable of filtering 95% of airborne particles. of They meet CDC guidelines for Mycobacterium tuberculosis exposure control. As disposable particulate respirators, they are intended to reduce wearer exposure to certain airborne particles including those generated by electrocautery, laser surgery, and other powered medical instruments. As surgical masks, they are designed to be fluid resistant to splash and spatter of blood and other infectious materials.

- NIOSH approved N95 rating
- FDA cleared for use as a surgical mask
- Fluid Resistance 80 mmHg
- Flammability Rating Class I
- Adjustable nose clip
- Braided and stapled headbands
- Particulate Respirator and Surgical Mask

2 PROTECTIVE N99

Capable of filtering 99% of airborne particles. of They meet CDC guidelines for Mycobacterium tuberculosis exposure control. As disposable particulate respirators, they are intended to reduce wearer exposure to certain airborne particles including those generated by electrocautery, laser surgery, and other powered medical instruments. As surgical masks, they are designed to be fluid resistant to splash and spatter of blood and other infectious materials.

- NIOSH approved N99 rating
- FDA cleared for use as a surgical mask
- Flammability Rating Class I
- Adjustable nose clip
- Braided and stapled headbands
- Particulate Respirator and Surgical Mask

3 3PLY-DISPOSABLE FACE MASK (95&98% BFE)

Disposable face (95&98% BFE) mask is great for protecting people from pollen, bacteria, allergens, dust, chemicals and smoke. Keep people stay healthy and safe when at work or out by protecting your airways from pollutants and allergens to help you breathe easier and stay germ free as much as possible.

- Water-repellent non-woven fabric, effective blocks visible objects such as droplets
- Meltblown non-woven, Filtered air containing bacteria suspended particles, BFE≥ 95-98%
- Non-woven fabric, Absorb the hot air exhaled from the body
- Plastic nose clip - Fits the bridge of nose
- Ultrasonic quality spot welding

4 4PLY-DISPOSABLE FACE MASK (99% BFE)

Disposable face (99% BFE) mask is great for protecting people from pollen, bacteria, allergens, dust, chemicals and smoke. Keep people stay healthy and safe when at work or out by protecting your airways from pollutants and allergens to help you breathe easier and stay germ free as much as possible.

- Water-repellent non-woven fabric, effective blocks visible objects such as droplets
- Meltblown non-woven, Filtered air containing bacteria suspended particles,
- BFE≥ 99%
- Non-woven fabric, Absorb the hot air exhaled from the body
- Plastic nose clip - Fits the bridge of nose
- Ultrasonic quality spot welding

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DISINFECTION & CLEANING

1 HAND SANITIZER GEL

Hand Sanitizer kills 99.9% of germs instantly. Use anytime, anywhere: while in car, office, handbag, picnics, nappy change, travel, sports etc. Leaves your hands refreshed. Use as often as required.

- Get clean hands anytime, anywhere no water necessary
- Soft, gentle moisturizing formula

2 UNIVERSAL WIPES

A combined detergent and disinfectant product helps lift and remove dirt and germs as well as killing any germs that left on a surface. Coronaviruses can survive on surface for many hours but are removed by cleaning and disifected

3 UNIVERSAL SPRAY

Universal spray for the disinfection and cleaning of non-invasive medical surface and equipment. the most effective fromula on the market. A mix of biocides with different mechanisms of action prevents bacterial resistance and superbug formation.

- Multi-purpose
- Skin friendly and dermetologically tested
- No damages to surfaces or equipment
- Simple, easy and reliable

DISPOSABLE EQUIPMENT

1 DISPOSABLE FACE SHIELD

Face Shields are an important piece of Personal Protective Equipment (PPE). Surgical Face Shields provide over the top, side, and front face protection against splash and splatter of fluid-borne pathogens.

- Polyester lens
- Treated with antifog and antistatic coating
- Headpiece is held in place by a stretch strap
- Includes a latex-free foam band for comfortable extended wear

2 DISPOSABLE SHOE COVER

Comfortable shoe covers are made of SMS fabric. Covers are available with or without skid-resistant tread.

- Single Use
- Nonslip, have a pvc sole which is completely sealed
- Knee-high, in order, be higher than bottom edge of the gown

3 DISPOSABLE SURGICAL HOOD

Comfortable hood conforms to the head and neck, providing maximum coverage for hair and sideburns. Adjustable ties at the neck offer a secure and comfortable fit. This surgical hood provides complete head coverage. Blue hood has gentle elastic at neck for a comfortable fit.

- Single Use
- Preferably fluid resistant

4 DISPOSABLE BOOTS COVER/OVERBOOTS

This overboot is soft and microporous, strong and resistant to chemical splash and dust and can be used for a wide range of applications. Boot incorporates a synthetic leather anti-slip sole.They are anti-static and lint free and are suitable for clean room applications. Reduces microbiological growth and contamination in aseptic conditions.

- Single Use
- Boots are universal size with elasticated top and ankle ties

DISPOSABLE EQUIPMENT

5 DISPOSABLE PP COVERALL

Designed to protect the wearer from injury or the spread of infection or illness.

- Single Use
- Provide full body coverage, Splash-resistent, keep dust and chemicals off clothes.
- Elastic cuff will prevent the dust from entering.
- Disposable coverall can provide long-lasting protection.

6 DISPOSABLE PP+PE COVERALL

Designed to protect the wearer from injury or the spread of infection or illness.

- Single Use
- Provide full body coverage, Splash-resistent, keep dust and chemicals off clothes.
- Elastic cuff will prevent the dust from entering.
- Disposable coverall can provide long-lasting protection.

7 DISPOSABLE SURGEON CAP

Easy-tie surgeon's cap is designed for particulate control. Our cap is easy to don and features adjustable ties. Lightweight, nonwoven material is comfortable and absorbent.

- Single Use
- Preferably fluid resistant
- Adjustable and immovable once adjusted

8 DISPOSABLE HAIR NET

Our Hair net are made of heavyweight spunbond polypropylene. They are designed to provide additional strength while still offering breathability and comfort. Synthetic elastic offers a personalized fit.

- Single Use
- Preferably fluid resistant
- Adjustable and immovable once adjusted

9 DISPOSABLE SURGICAL GOWN

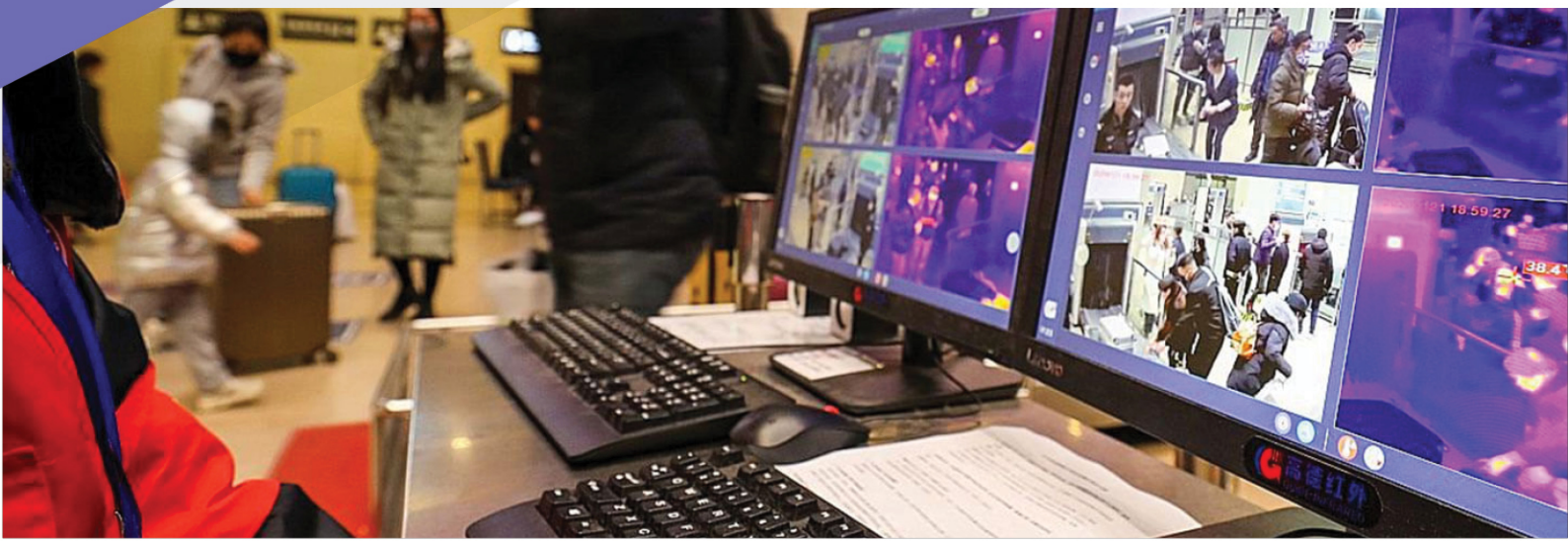
One of the most important protective items during surgical procedures, surgical gowns play a vital role in maintaining aseptic conditions by preventing transfer of harmful micro-organisms, fluids and chemicals to and from the patient. Good quality surgical gown keeps bacteria from entering surgical wounds and at the same time protect surgeons and nurses against bodily fluids, bloods, secretion, excretion during surgical procedures.

10 DISPOSABLE CPE APRON

Suitable for food processing, home cleaning, beauty salons, medical and chemical tests, industrial and agricultural workmanship and protection, painting and painting etc.

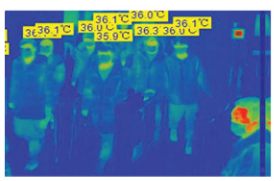
- single-use
- Made of polyester with pvc-coated
- Waterproof, oil proof, acid and alkali resistant, anti bacteria, non-toxic, tasteless, disposable, hygienic and environmental protection.

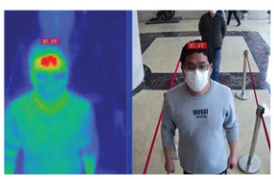
IR THERMAL FEVER DETECTION SYSTEM



Higher efficiency on temperature detection

Temperature screening from 2~10 meters away





Automatic warning, photo capturing and storage while detecting the fever

1 IR THERMAL FEVER DETECTION SYSTEM (IRTC-G2)

IRTC-G2 IS Hi Accuracy, Real-Time Face Recognition, Multi-Target, Back-tracking, Automated Detection System with Visual Alarm. I R T C - G 2 IR Fever Warning System can be applied to mass fever screening in crowded public places, which help to detect people with a potential fever and may contain or limit the spread of the COVID-19 through identification of infected individuals showing fever symptoms. IRTC-G2 combines advanced technology such as thermo-graphy human temperature measurement algorithm and AI intelligent face recognition to make the equipment accurate and easy to use.

Its equipped with various powerful functions. Multi-target tracking can ensure that no targets are missed. Custom warning zones and hightemperature shielding settings can avoid interference from other high-temperature objects. When detect the febrile people, it supports automatic warning, tracking and photo taking for storage. Support video recording. Convenient to query and classify management. It is the ideal equipment for epidemic prevention in public places such as airports, stations, factories, schools, commercial centers and more.

FEATURES

- Adopts 384x288-400x300 infrared uncooled Vox detector
- AI deep learning algorithm based on neural network, more accurate
  temperature measurement and lower false warning rate
- Accurate single/multi-point high temperature tracking and warning
- Equipped with black body, real-time temperature calibration, higher accuracy
- Face recognition detection function, more intelligent
- Stand-type, easy to move, standard PC with powerful analysis software

DISCLAIMER NOTICE

General

The information provided by XFYRE, is for general informational purposes only. All information on the Brochure is provided in good faith, however we make no representation or warranty of any kind, express or implied, regarding the accuracy, adequacy, validity, reliability, availability or completeness of any information on the Brochure. UNDER NO CIRCUMSTANCE SHALL WE HAVE ANY LIABILITY TO YOU FOR ANY LOSS OR DAMAGE OF ANY KIND INCURRED AS A RESULT OF THE USE OF THE BROCHURE OR RELIANCE ON ANY INFORMATION PROVIDED ON THE BROCHURE. YOUR USE OF THE BROCHURE AND YOUR RELIANCE ON ANY INFORMATION ON THE BROCHURE IS SOLELY AT YOUR OWN RISK.

Product

Despite every effort to provide accurate images of each product's colour and design, actual colours and design may vary slightly, due to different device screen settings, the lighting in the installation location, slight differences in product finishes over time and other factors.

XFYRE will not accept responsibility for any colour or design differences that are not factory faults. In purchasing from XFYRE, you agree to accept the small risk that there will be a slight variation between the actual colour and design, and the representation on our brochure.

In addition, please be aware that colours and textured finishes often vary between manufacturers; for example, slightly different shades and degrees of 'Blue'.

Dimension

The dimension provided on this brochure is for general information purposes and use only.

Every endeavour is made to keep the product information complete and correct, however the customer is responsible for ensuring the product they purchase is suitable for their specific requirements.

We make every effort to give you accurate information regarding manufacturer reported sizing information and dimensions for our products in our size guides. However, please note that due to the nature of the manufacturing process and due to measurements made manually from time to time product sizing could vary. XFYRE is not responsible for sizing variations in the manufacturing process or the packaging.

MEDICAL EQUIPMENT CERTIFICATION

Medical Equipment

CERTIFIED

according to the following standards:

No. Siri: 006090
Serial No.:

ASAL
ORIGINAL

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
LESEN ESTABLISMEN
ESTABLISHMENT LICENCE
Seksyen 15(1) Akta 737
Section 15(1) of Act 737

No. Lesen / Licence No. : MDA-1214-K120
Tarikh Sah Lesen / Licence Validity Date : 07/09/2020 - 06/09/2023

Lesen adalah dengan ini diberi kepada: / Licence is hereby granted to: XFYRE (M) SDN. BHD.

yang beralamat di: / of: NO.26 JALAN SUNGAI JELUH 32/192, KAWASAN PERINDUSTRIAN KEMUNING, SEKSYEN 32, 42460 SHAH ALAM SELANGOR

Sebagai: / as: PEMBUAT / MANUFACTURER

Orang yang bertanggungjawab: / Person Responsible: KHAMIL ISMAIL

Lesen ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan dibawahnya serta syarat-syarat seperti di Lampiran 1.
This licence is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 1.

AHMAD SHARIFF BIN HAMBALI
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

Medical Device AUTHORITY MALAYSIA

MEDICAL DEVICE AUTHORITY

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

CERTIFICATIONS

CARE Certification International

XFYRE (M) SDN BHD

2020 Valid with sticker ONLY 2021 Valid with sticker ONLY 2022

Certificate No. : MYQ11206703

This certificate has been
Awarded to
XFYRE (M) SDN BHD
Which is located at
NO. 26, JALAN SUNGAI JELUH 32/192, KAWASAN PERINDUSTRIAN KEMUNING, SEKSYEN 32, 42460 SHAH ALAM, SELANGOR, MALAYSIA.

On Standard
ISO 9001 : 2015

Which the organization stated above had been assessed and found to be in accordance with the requirements of international Quality Management System.
XFYRE (M) SDN BHD
Under the Scope of

I) PROVISION OF SERVICE OF DEFENSIVE AND SECURITY SYSTEM, INCLUDING SATELLITE COMMUNICATION, BUILDING APPLICATION, FIREWALL, BODY ARMOR, SURVEILLANCE & COUNTER SURVEILLANCE, VEHICLE ARMORING, POWER SYSTEM SOLUTION, TELECOMMUNICATION, CORE TECHNOLOGY, AND FORENSICS.
II) PROVISION OF MANUFACTURING OF PPE AND SINGLE-USE MEDICAL DEVICE, INCLUDING DISPOSABLE FACE SHIELD, SHOE COVER, DISPOSABLE HEAD COVER - DISPOSABLE SURGICAL HOOD, SHOE COVER/ OVERBOOTS, DISPOSABLE COVERALL, DISPOSABLE SURGEON CAP, DISPOSABLE HAIR NET, NITRILE DISPOSABLE GLOVES, LATEX DISPOSABLE GLOVES, SURGICAL GOWNS, PROTECTIVE N95, MEDICAL N99, DISPOSABLE FACE MASK, DISPOSABLE CPE APRON, HAND SANITIZER GEL, UNIVERSAL SPRAY AND UNIVERSAL WIPES.

Original Issued Date : 19th November 2020
Effective Date : 19th November 2020
Expiration Date : 18th November 2023

This certificate will be null and void if at any circumstances the compliance towards the standards of ISO 17021 is not fulfilled. The compliance of the standards stated above will be indicated by the labelling on the right corner indicating the year of assessment. The validity of the certificate can also be traced to the audit report generated for each every assessment or through our website www.carecert.net

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT
STANDARDS MALAYSIA ACCREDITED
ACB QMS 13

Fleming Teo
Managing Director
CARE Certification International (M) Sdn. Bhd.

CARE Certification International (M) Sdn. Bhd.
No. 3-16, IOI Boulevard, Jalan Kenari 6, Bandar Puchong Jaya, 47170 Puchong, Selangor Darul Ehsan, Malaysia.

CARE Certification International

XFYRE (M) SDN BHD

Certificate No. : MYMD8206481

This certificate has been
Awarded to
XFYRE (M) SDN BHD 1050175-D
Which is located at
NO. 26, JALAN SUNGAI JELUH 32/192, KAWASAN PERINDUSTRIAN KEMUNING, SEKSYEN 32, 42460 SHAH ALAM, SELANGOR, MALAYSIA.

On Standard
ISO 13485 : 2016

Which the organization stated above had been assessed and found to be in accordance with the requirements of international Quality Management System for Medical Device.
XFYRE (M) SDN BHD
Under the Scope of

MANUFACTURING (OUTSOURCED) OF PERSONAL PROTECTIVE EQUIPMENT AND SINGLE-USE MEDICAL DEVICES - DISPOSABLE FACE SHIELD, SHOECOVER, HEADCOVER-DISPOSABLE SURGICALHOOD, BOOTS COVER / OVERBOOTS, DISPOSABLE COVERALL, DISPOSABLE SURGEON CAP, DISPOSABLE HAIR NET, NITRILE GLOVES, LATEX GLOVES, SURGICAL GLOVES, SURGICAL GOWN, PROTECTIVE N95 & MEDICAL N99, 3-PLY DISPOSABLE FACE MASK, AND DISPOSABLE CPE APRON.

Original Issued Date : 27th August 2020
This Certificate Validity will be until : 26th August 2021

This certificate will be null and void if at any circumstances the compliance towards the standards stated above. The validity of the certificate can also be traced to the audit report generated for each every assessment or through our website www.carecert.net

STANDARDS MALAYSIA ACCREDITED
ACB MDMS 03

Fleming Teo
Managing Director
CARE Certification International (M) Sdn. Bhd.

CARE Certification International (M) Sdn. Bhd.
No. 3-16, IOI Boulevard, Jalan Kenari 6, Bandar Puchong Jaya, 47170 Puchong, Selangor Darul Ehsan, Malaysia.

2021

CERTIFICATE OF REGISTRATION

This certifies that:

XFYRE (M) SDN BHD
No. 26 Jalan Sungai Jeluh 32/192
Seksyen 32 Kawasan Perindustrian Kemuning
Shah Alam Selangor, MY 42460

is registered with the U.S. Food and Drug Administration for FY 2021 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	**3017196093**
Device Classification Name:	**POLYMER PATIENT EXAMINATION GLOVE**
Product Code:	**LZA**
Regulation Number:	**880.6250**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

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info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: November 18, 2020

FDA

FOOD AND DRUG ADMINISTRATION

(POLYMER PATIENT EXAMINATION GLOVE)

(LATEX PATIENT EXAMINATION GLOVE)

(FACE MASK FOOR GENERAL PUBLIC/HEALTHCARE PERSONAL PER IIE GUIDANCE)

2021

CERTIFICATE OF REGISTRATION

This certifies that:

XFYRE (M) SDN BHD
No. 26 Jalan Sungai Jeluh 32/192
Seksyen 32 Kawasan Perindustrian Kemuning
Shah Alam Selangor, MY 42460

is registered with the U.S. Food and Drug Administration for FY 2021 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	**3017196093**
Device Classification Name:	**LATEX PATIENT EXAMINATION GLOVE**
Product Code:	**LYY**
Regulation Number:	**880.6250**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

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info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: November 18, 2020

2021

CERTIFICATE OF REGISTRATION

This certifies that:

XFYRE (M) SDN BHD
No. 26 Jalan Sungai Jeluh 32/192
Seksyen 32 Kawasan Perindustrian Kemuning
Shah Alam Selangor, MY 42460

is registered with the U.S. Food and Drug Administration for FY 2021 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	**3017196093**
Device Classification Name:	**FACE MASK (EXCEPT N95 RESPIRATOR) FOR GENERAL PUBLIC/HEALTHCARE PERSONNEL PER IIE GUIDANCE**
Product Code:	**QKR**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

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David Lennarz
Executive Director
Registrar Corp
Dated: November 18, 2020

ASTM INTERNATIONAL

AMERICAN SOCIETY FOR TESTING AND MATERIALS

(NITRILE EXAMINATION GLOVES FOR MEDICAL)

CERTIFICATIONS

SIRIM QAS International Sdn. Bhd.
(Company No.: 199601037981 (410334-X))
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40700 Shah Alam, Selangor Darul Ehsan, Malaysia
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Fax: 03-55446688
www.sirim-qas.com.my

TEST REPORT

REPORT NO : 2021CE0119	PAGE : 1 OF 3

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THIS TEST REPORT IS ISSUED IN SECURED PDF SOFTCOPY

Applicant	: XFYRE (M) SDN. BHD. NO. 26, JALAN SUNGAI JELUH 32/192, KAWASAN PERINDUSTRIAN KEMUNING, 42460 SHAH ALAM, SELANGOR, MALAYSIA
Manufacturer	: XFYRE (M) SDN. BHD. NO. 26, JALAN SUNGAI JELUH 32/192, KAWASAN PERINDUSTRIAN KEMUNING, 42460 SHAH ALAM, SELANGOR, MALAYSIA
Product	: THERACOM SAFEGLOVES
Reference Standard / Method of Test	: ASTM D6124 - 06(2017) Standard Test Method for Residual Powder on Medical Gloves (Procedure I: Quantitation of Powder on Powder-free Gloves)
Description of sample	: Received one (1) sample THERACOM SAFEGLOVES for testing which was not labelled.
Date Received of Complete Application	: 15 January 2021
Job No.	: J20211400072
Description of Test Results	: The test result of the submitted test sample is described in Page 2 of this test report.
Issued Date	: 22 January 2021

Approved Signatory;

IKM M/5292/8660/20

(MUHAMMAD ZUHAIRI BIN BORHAN)
Testing Executive

SIRIM QAS International Sdn. Bhd. CHEMICAL & CONSUMER SECTION

(HAHNAS BINTI MAHBUT)
Head
Chemical & Consumer Section
Testing Services Department

REPORT NO : 2021CE0119	PAGE : 2 OF 3

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TEST RESULTS

Product : **THERACOM SAFEGLOVES**
Test Method : **ASTM D6124 - 06(2017) Standard Test Method for Residual Powder on Medical Gloves (Procedure I: Quantitation of Powder on Powder-free Gloves)**

No.	Type of Test	Result
1.	Residual Powder, mg	Nil

SIRIM QAS International Sdn. Bhd. CHEMICAL & CONSUMER SECTION

REPORT NO : 2021CE0119	PAGE : 3 OF 3

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1. A Test Report will be issued in respect of Testing Services conducted and shall relate only to the sample actually tested. SIRIM QAS International makes no warranty whatsoever and the Applicant shall not represent in any manner that any duplication or mass production of the Product is same as the sample actually tested or that SIRIM QAS International has tested any of the duplicated or mass-produced Product. Measurement uncertainty shall be included in the Test Report when there is no statement of conformity required. When a statement of conformity to a specification or standard is applied, the Simple Acceptance Rule is used. Unless otherwise stated, the Acceptance Rule with Guard Band is used.
2. The Test Report shall not be misused, amended, changed, varied or modified in any manner whatsoever by the Applicant or otherwise.
3. If the Test Report is to be furnished to any third party or to the public, each such Test Report shall be furnished in full, legible and in its entirety.
4. The Test Report shall not be reproduced and shall not in any event be used for any advertising purposes or whatsoever without written approval from the Head of Quality, Occupational Safety and Health & Environment (QOSHE) of SIRIM QAS International of No 1, Persiaran Dato' Menteri, Building 8, Section 2, P.O. Box 7035, 40700 Shah Alam, Selangor Darul Ehsan.
5. Customer (Applicant/Manufacturer/Factory,etc.) is not permitted to use any SIRIM QAS International, SIRIM or other SIRIM's subsidiaries logo or words on packaging, sample's manual, technical specification, items and products.
6. Subject to consent and written approval from the Head of Quality, Occupational Safety and Health & Environment (QOSHE) of SIRIM QAS International, the customer (Applicant/Manufacture/Factory,etc.) may use SIRIM QAS International logo or word on the promotional materials and the Applicant shall only include the phrase, "A sample of this product has been tested by SIRIM QAS International ...(Test Report No) ...(dated) ...(for what test) ...(to which standard)" or such similar words which stress that only the sample was actually tested. This phrase shall only be used for the purpose of product advertisement or product promotion (eg; brochures/flyers/official website). For avoidance of doubt, the statement shall not be used on the sample, packaging of the sample, items and products.
7. In the event there is an investigation from a Government Regulatory Agency concerning the Applicant's Test Report, SIRIM QAS International may disclose the information pertaining to the Test Report for purposes of such investigation.
8. Further or in the alternative, it is strictly forbidden unless with prior written approval from the Chief Executive Officer of SIRIM QAS International, to represent in any manner whatsoever that SIRIM QAS International, SIRIM and/or other SIRIM's subsidiaries has endorsed, approved or validated the Product of the Applicant in any manner whatsoever.
9. In the event the Applicant is found in breach of this provision, SIRIM QAS International, SIRIM and/or other SIRIM's subsidiaries without prejudice to any other rights and remedies may take whatever action necessary including but not limited to:
   a) Informing and placing a notice in the media;
   b) Obtaining an injunction from Court (cost on a solicitor-client basis to be borne by the Applicant);
   c) Refusing to accept any further Product for Testing Services from the Applicant or whosoever related to the Applicant, whether subsidiary or otherwise;
   d) Instructing the Applicant to withdraw and recall the advertisement, statement or document in question and advertise a clarification and apology to SIRIM QAS International, SIRIM and/or other SIRIM's subsidiaries twice in a national publication of SIRIM QAS International's choice at the Applicant's sole cost; and
   e) Informing or lodging a report pertaining the Applicant's Test Report with the relevant authorities.
10. SIRIM QAS International is committed in supporting an environmentally-friendly business practices by reducing paper consumption, therefore we do not issue any hard copy of Test Report to the Applicant. However, additional certified true copy(ies) or softcopy of the Test Report may be issued upon request by the Applicant upon payment of the relevant fee. The certified true copy(ies) or softcopy of test report shall only be given for test report issued not more than three (3) years from the date of issuance.
11. Issuance of Amendment Report due to the following reasons are chargeable to the Applicant :
    a) Changes in details of the Applicant name and/or address;
    b) Changes in details of the Manufacturer's name and/or address;
    c) Changes in details of the Factory location name and/or address;
    d) Changes in details of the model and/or type designation
12. However, issuance of Supplementary Report due to the following reasons are FOC :
    a) Misprints and typo errors;
    b) Missing technical information as agreed in PP1 form;
    c) Test data not reported;
    d) Mistake in reporting of test data
13. Corrections to report shall only be allowed if the date of issuance of the original report has not exceeded 6 months and shall be limited to a maximum 3 times, after either case whichever occurs earlier, an Amendment or a Supplementary Report shall not be issued.

SIRIM QAS INTERNATIONAL

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TEST REPORT

REPORT NO : 2020CE1187	PAGE : 1 OF 3

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Applicant	: XFYRE (M) SDN. BHD., No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor Darul Ehsan, Malaysia
Manufacturer	: Not Stated
Product	: Safegloves
Reference Standard / Method of Test	: ASTM D 6319 - 10 - Title: Standard Specification for Nitrile Examination Gloves for Medical Application
Description of sample	: Received one (1) sample of Safegloves for testing which was identified as: Brand: THERACOM Product Description: Disposable Gloves
Date Received of Complete Application	: 30 July 2020
Job No.	: J20201400856
Description of Test Results	: This test report covers only test clauses as requested by Applicant to SIRIM QAS International Sdn. Bhd. The test results for the submitted test sample as described in this test report complied with the requirement of the above reference standard at the respective clauses tested
Issued Date	: 11 September 2020

Approved Signatory;

(MUHAMMAD RIZAL BIN ABDUL RAHIM)
Senior Testing Executive

SIRIM QAS International Sdn Bhd CHEMICAL & CONSUMER SECTION

(HAHNAS BINTI MAHBUT)
Head
Chemical & Consumer Section
Testing Services Department

ASTM INTERNATIONAL

AMERICAN SOCIETY FOR TESTING AND MATERIALS

(NITRILE EXAMINATION GLOVES FOR MEDICAL)

CERTIFICATIONS

REPORT NO : 2020CE1187	PAGE : 2 OF 3

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Test Results:

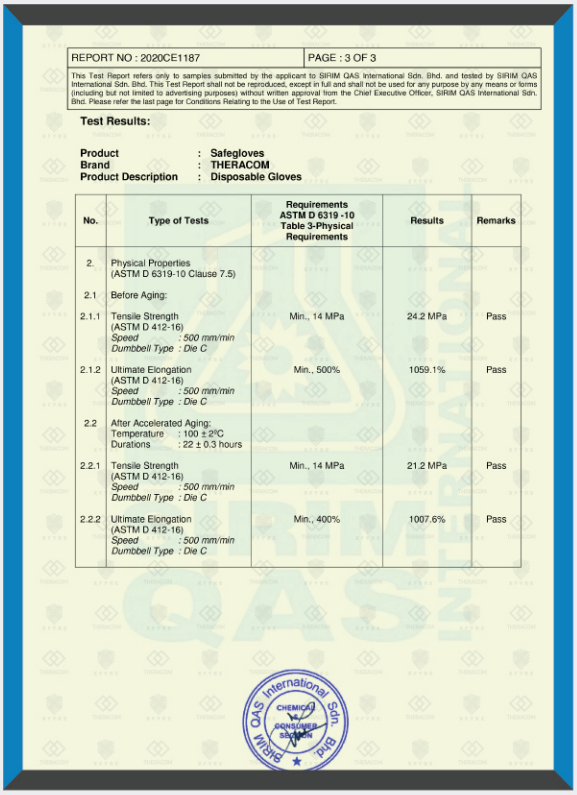
Product : Safegloves
Brand : THERACOM
Product Description : Disposable Gloves

No.	Type of Tests	Requirements ASTM D 6319 -10 Table 1-Performance Requirements	Results	Remarks
1.	Sterility (ASTM D 6319-10 Clause 7.2)	No fails sterility	Not Applicable	*
2.	Freedom from holes (ASTM D 6319-10 Clause 7.3 & ASTM D 5151)	Free from holes	No holes detected (No water leakage observed)	Pass

No.	Type of Tests	Requirements ASTM D 6319 -10 Table 2-Dimensions and Tolerances	Results	Remarks
3.	Dimensions (ASTM D 6319-10 Clause 7.4)	Size Medium (M):	Size Medium (M):	
3.1	Width	95±10mm	95mm	Pass
3.2	Length	Min., 230mm	234mm	Pass
3.3	Thickness:			
3.3.1	Finger	Min., 0.05mm	0.14mm	Pass
3.3.2	Palm	Min., 0.05mm	0.10mm	Pass

*Note: * No sterile labeled*

SIRIM QAS International Sdn Bhd CHEMICAL & CONSUMER SECTION



REPORT NO : 2020CE1187	PAGE : 3 OF 3

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Test Results:

Product : Safegloves
Brand : THERACOM
Product Description : Disposable Gloves

No.	Type of Tests	Requirements ASTM D 6319 -10 Table 3-Physical Requirements	Results	Remarks
2.	Physical Properties (ASTM D 6319-10 Clause 7.5)			
2.1	Before Aging:			
2.1.1	Tensile Strength (ASTM D 412-16) *Speed : 500 mm/min* *Dumbbell Type : Die C*	Min., 14 MPa	24.2 MPa	Pass
2.1.2	Ultimate Elongation (ASTM D 412-16) *Speed : 500 mm/min* *Dumbbell Type : Die C*	Min., 500%	1059.1%	Pass
2.2	After Accelerated Aging: Temperature : 100 ± 2°C Durations : 22 ± 0.3 hours			
2.2.1	Tensile Strength (ASTM D 412-16) *Speed : 500 mm/min* *Dumbbell Type : Die C*	Min., 14 MPa	21.2 MPa	Pass
2.2.2	Ultimate Elongation (ASTM D 412-16) *Speed : 500 mm/min* *Dumbbell Type : Die C*	Min., 400%	1007.6%	Pass

SIRIM QAS International Sdn Bhd CHEMICAL & CONSUMER SECTION

ASTM INTERNATIONAL

AMERICAN SOCIETY FOR TESTING AND MATERIALS

(ASTM F1862 - SYNTHETIC BLOOD PENETRATION)

CERTIFICATIONS

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TEST REPORT

REPORT NO : 2021CE0089	PAGE : 1 OF 4

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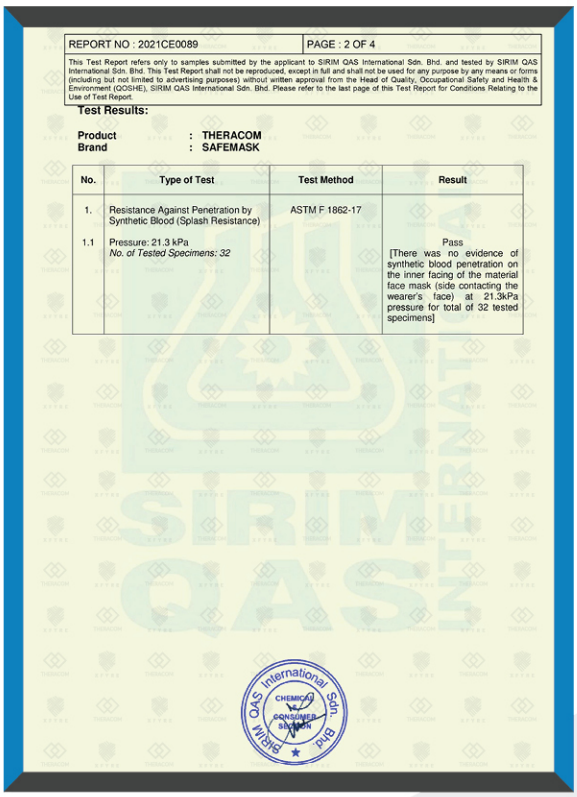
Applicant	: XFYRE (M) SDN. BHD., No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor Darul Ehsan, Malaysia
Manufacturer	: XFYRE (M) SDN. BHD., No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor Darul Ehsan, Malaysia
Product	: THERACOM
Reference Standard / Method of Test	: ASTM F1862 / F1862M - 17 -Title: Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
Description of sample	: Received one (1) sample of THERACOM for testing which was identified as; Brand: SAFEMASK
Date Received of Complete Application	: 22 December 2020
Job No.	: J20201401695
Description of Test Results	: This test report covers only test clauses as requested by Applicant to SIRIM QAS International Sdn. Bhd. The test results for the submitted test sample are described in next pages of this test report
Issued Date	: 15 January 2021

Approved Signatory;

(MUHAMMAD RIZAL BIN ABDUL [illegible])
Senior Testing Executive

SIRIM QAS International Sdn Bhd CHEMICAL & CONSUMER SECTION

(HAHNAS BINTI MAHBUT)
Head
Chemical & Consumer Section
Testing Services Department



REPORT NO : 2021CE0089	PAGE : 2 OF 4

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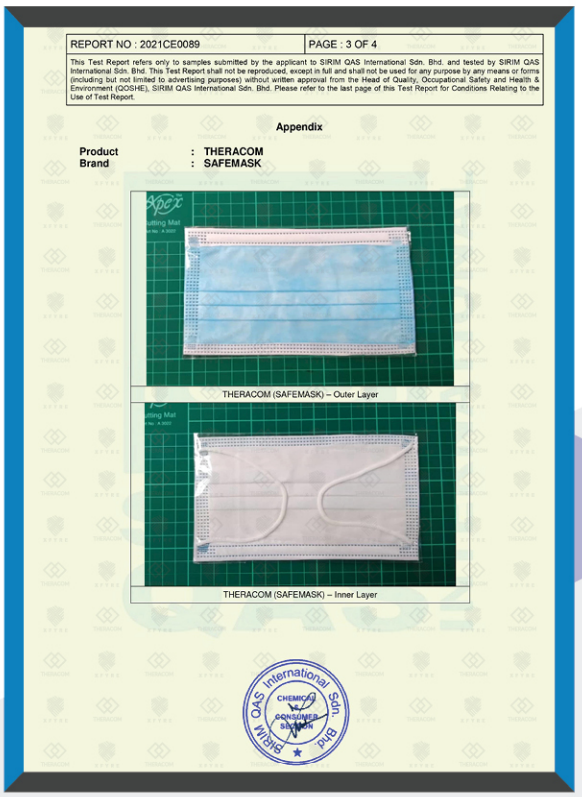
Test Results:

Product : THERACOM
Brand : SAFEMASK

No.	Type of Test	Test Method	Result
1.	Resistance Against Penetration by Synthetic Blood (Splash Resistance)	ASTM F 1862-17	
1.1	Pressure: 21.3 kPa *No. of Tested Specimens: 32*		Pass [There was no evidence of synthetic blood penetration on the inner facing of the material face mask (side contacting the wearer's face) at 21.3kPa pressure for total of 32 tested specimens]

SIRIM QAS International Sdn Bhd CHEMICAL & CONSUMER SECTION



REPORT NO : 2021CE0089	PAGE : 3 OF 4

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Appendix

Product : THERACOM
Brand : SAFEMASK

THERACOM (SAFEMASK) – Outer Layer

THERACOM (SAFEMASK) – Inner Layer

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TEST REPORT

REPORT NO : 2021CE0088	PAGE : 1 OF 4

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Applicant	: XFYRE (M) SDN. BHD., No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor Darul Ehsan, Malaysia
Manufacturer	: XFYRE (M) SDN. BHD., No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor Darul Ehsan, Malaysia
Product	: THERACOM
Reference Standard / Method of Test	: ISO 22609:2004-Title: Clothing for Protection against Infectious Agents-Medical Face Masks-Test Method for Resistance Against Penetration by Synthetic Blood (Fixed Volume, Horizontally Projected)
Description of sample	: Received one (1) sample of THERACOM for testing which was identified as: Brand: SAFEMASK
Date Received of Complete Application	: 22 December 2020
Job No.	: J20201401695
Description of Test Results	: This test report covers only test clauses as requested by Applicant to SIRIM QAS International Sdn. Bhd. The test result for the submitted test sample are described in next pages of this test report
Issued Date	: 15 January 2021

Approved Signatory;

(MUHAMMAD RIZAL BIN ABDUL RAHIM)
Senior Testing Executive

SIRIM QAS International Sdn Bhd. CHEMICAL & CONSUMER SECTION

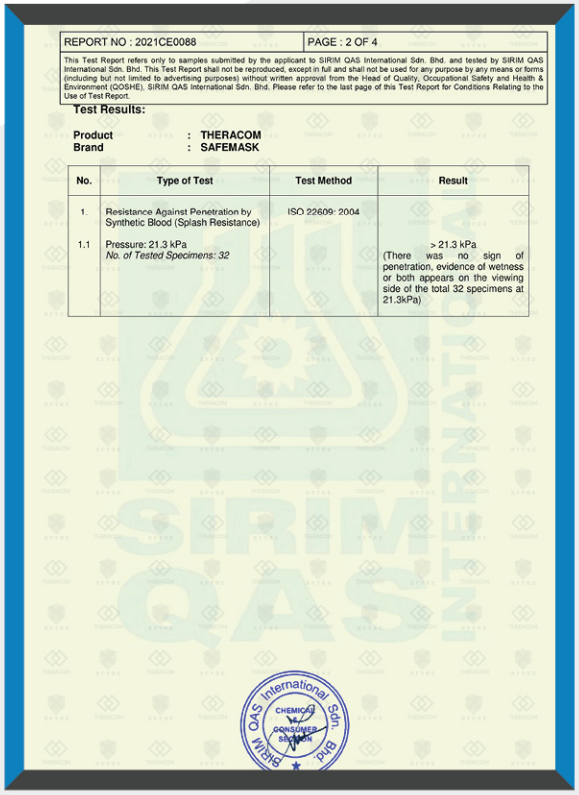
(HAHNAS BINTI MAHBUT)
Head
Chemical & Consumer Section
Testing Services Department

ISO

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

(ISO 22609 - SYNTHETIC BLOOD PENETRATION)

CERTIFICATIONS



REPORT NO : 2021CE0088	PAGE : 2 OF 4

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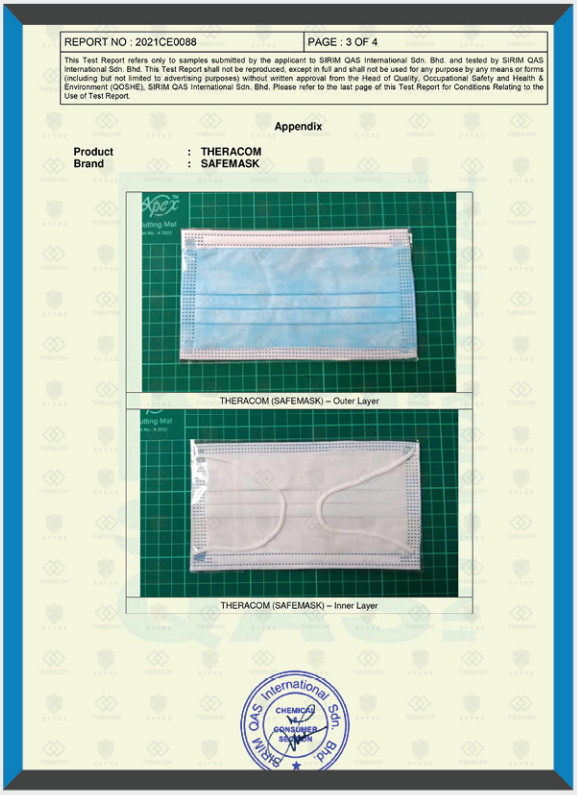
Test Results:

Product : THERACOM
Brand : SAFEMASK

No.	Type of Test	Test Method	Result
1.	Resistance Against Penetration by Synthetic Blood (Splash Resistance)	ISO 22609: 2004	
1.1	Pressure: 21.3 kPa *No. of Tested Specimens: 32*		> 21.3 kPa (There was no sign of penetration, evidence of wetness or both appears on the viewing side of the total 32 specimens at 21.3kPa)

SIRIM QAS International Sdn Bhd. CHEMICAL & CONSUMER SECTION



REPORT NO : 2021CE0088	PAGE : 3 OF 4

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Appendix

Product : THERACOM
Brand : SAFEMASK

THERACOM (SAFEMASK) – Outer Layer

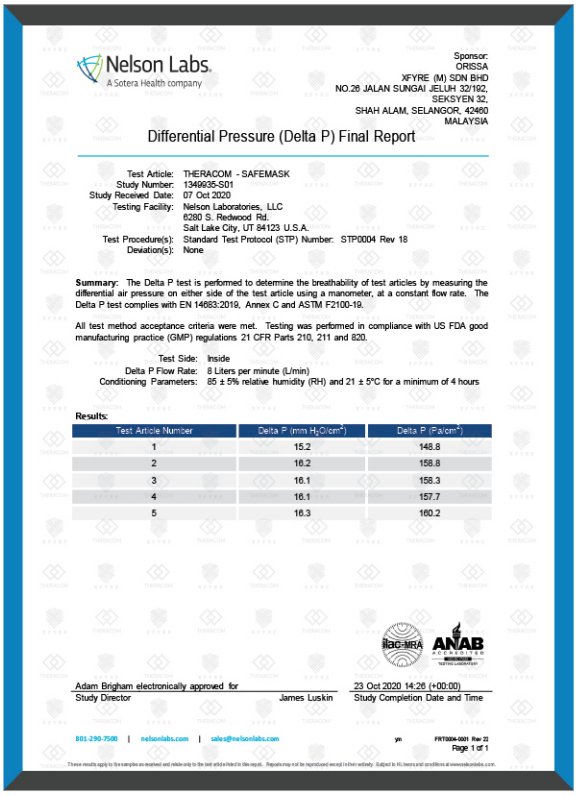
THERACOM (SAFEMASK) – Inner Layer

SIRIM QAS International Sdn Bhd. CHEMICAL & CONSUMER SECTION

Nelson Labs.
A Sotera Health company

NELSON LABS (DIFFERENTIAL PRESSURE) (FILTRATION EFFICIENCY)

CERTIFICATIONS



Nelson Labs.
A Sotera Health company

Sponsor:
ORISSA
XFYRE (M) SDN BHD
NO.26 JALAN SUNGAI JELUH 32/192,
SEKSYEN 32,
SHAH ALAM, SELANGOR, 42460
MALAYSIA

Differential Pressure (Delta P) Final Report

Test Article: THERACOM - SAFEMASK
Study Number: 1349935-S01
Study Received Date: 07 Oct 2020
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s): None

Summary: The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Inside
Delta P Flow Rate: 8 Liters per minute (L/min)
Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours

Results:

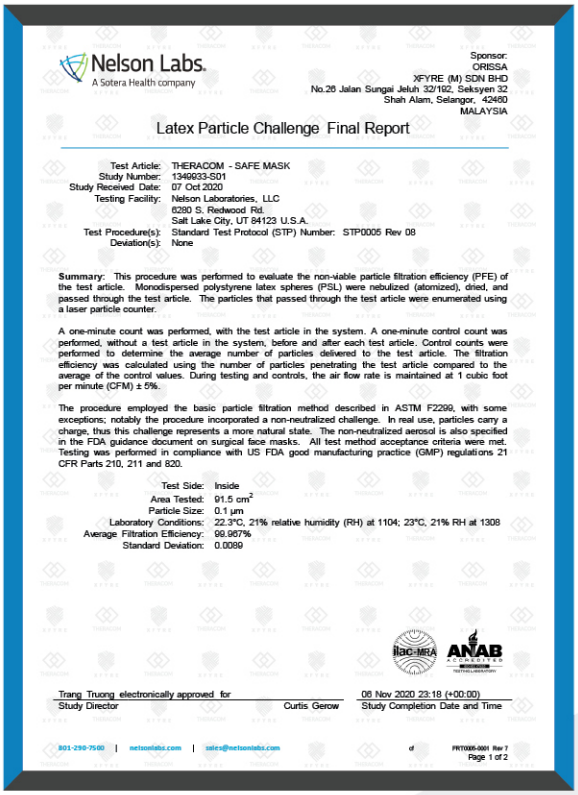
Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	15.2	148.8
2	16.2	158.8
3	16.1	158.3
4	16.1	157.7
5	16.3	160.2

Adam Brigham electronically approved for
Study Director James Luskin

23 Oct 2020 14:26 (+00:00)
Study Completion Date and Time

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com

FRT0004-0001 Rev 22
Page 1 of 1



Nelson Labs.
A Sotera Health company

Sponsor:
ORISSA
XFYRE (M) SDN BHD
No.26 Jalan Sungai Jeluh 32/192, Seksyen 32
Shah Alam, Selangor, 42460
MALAYSIA

Latex Particle Challenge Final Report

Test Article: THERACOM - SAFE MASK
Study Number: 1349933-S01
Study Received Date: 07 Oct 2020
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0005 Rev 08
Deviation(s): None

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values. During testing and controls, the air flow rate is maintained at 1 cubic foot per minute (CFM) ± 5%.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

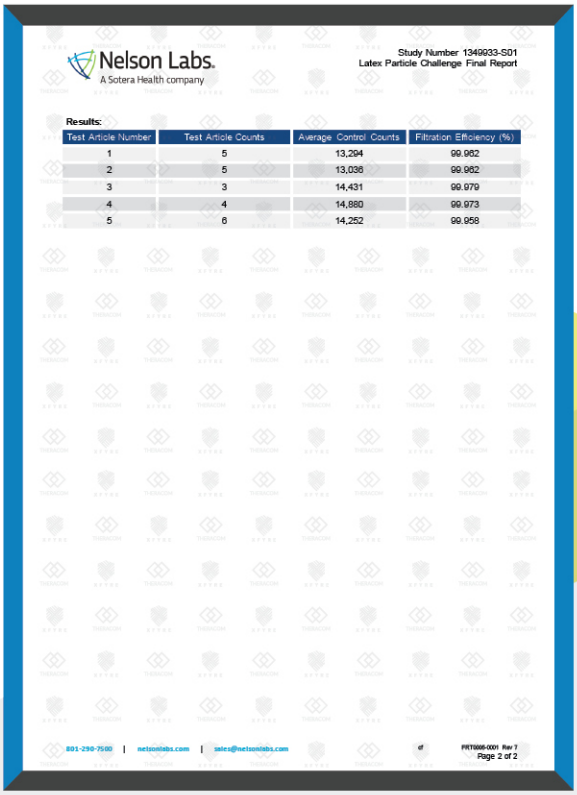
Test Side: Inside
Area Tested: 91.5 cm^2
Particle Size: 0.1 µm
Laboratory Conditions: 22.3°C, 21% relative humidity (RH) at 1104; 23°C, 21% RH at 1308
Average Filtration Efficiency: 99.987%
Standard Deviation: 0.0089

Trang Truong electronically approved for
Study Director Curtis Gerow

06 Nov 2020 23:18 (+00:00)
Study Completion Date and Time

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com

FRT0005-0001 Rev 7
Page 1 of 2



Nelson Labs.
A Sotera Health company

Study Number 1349933-S01
Latex Particle Challenge Final Report

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	5	13,294	99.962
2	5	13,036	99.962
3	3	14,431	99.979
4	4	14,880	99.973
5	6	14,252	99.958

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FRT0005-0001 Rev 7
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Certifications

GOOD DISTRIBUTION PRACTISE FOR MEDICAL DEVICE

NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH

(PROTECTIVE N95)

CERTIFICATIONS

CARE Certification International

CERTIFICATE OF CONFORMITY

GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICE

This is to certify : XFYRE (M) SDN BHD 1050175-D

Address : No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor, Malaysia.

Certificate Number : MYG12206710

Scope of Certification : Local Authorized Representative, Import, Distribution (Including Transportation), Storage And Handling, And Documentation (Including Traceability Of Medical Device) As Listed In Annex 1.

Outsource Process : Transportation.

Special Storage : No Special Storage.

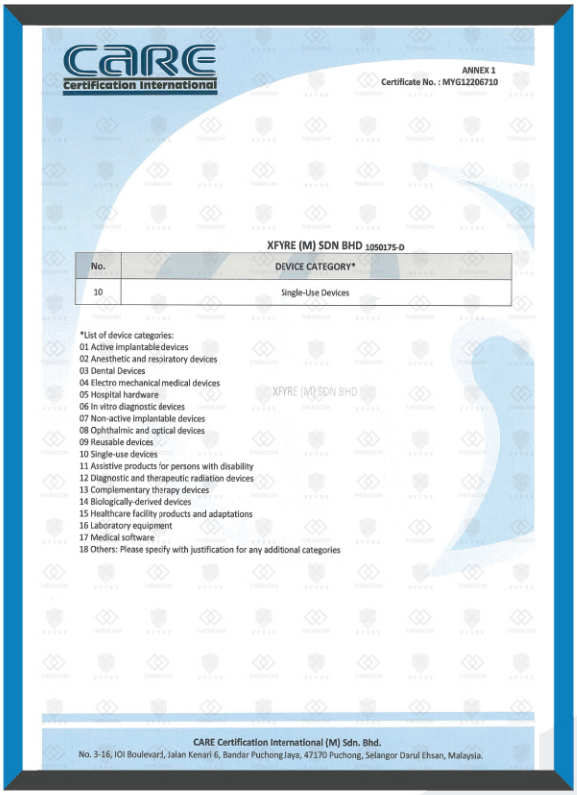
Certificate Issue Date : 3rd December 2020

Expiration Date : 2nd December 2021

This certificate will be null and void if at any circumstances the compliance towards the standards stated above. The validity of the certificate can also be traced to the audit report generated for each every assessment or through our website www.carecert.net

CAB Registration No. : MDA/CAB 009

Fleming Teo
Managing Director
CARE Certification International (M) Sdn. Bhd.



CARE Certification International

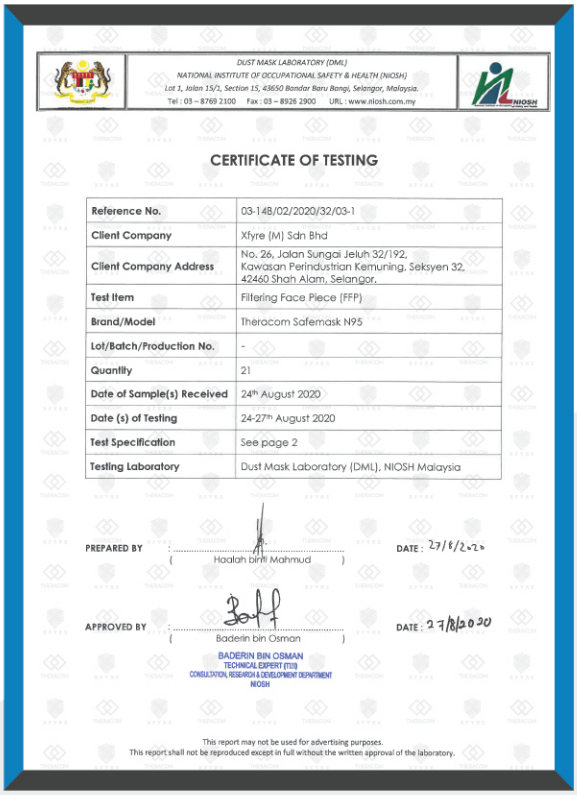
ANNEX 1
Certificate No. : MYG12206710

XFYRE (M) SDN BHD 1050175-D

No.	DEVICE CATEGORY*
10	Single-Use Devices

*List of device categories:
01 Active implantable devices
02 Anesthetic and respiratory devices
03 Dental Devices
04 Electro mechanical medical devices
05 Hospital hardware
06 In vitro diagnostic devices
07 Non-active implantable devices
08 Ophthalmic and optical devices
09 Reusable devices
10 Single-use devices
11 Assistive products for persons with disability
12 Diagnostic and therapeutic radiation devices
13 Complementary therapy devices
14 Biologically-derived devices
15 Healthcare facility products and adaptations
16 Laboratory equipment
17 Medical software
18 Others: Please specify with justification for any additional categories

CARE Certification International (M) Sdn. Bhd.
No. 3-16, IOI Boulevard, Jalan Kenari 6, Bandar Puchong Jaya, 47170 Puchong, Selangor Darul Ehsan, Malaysia.



DUST MASK LABORATORY (DML)
NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY & HEALTH (NIOSH)
Lot 1, Jalan 15/1, Section 15, 43650 Bandar Baru Bangi, Selangor, Malaysia.
Tel : 03 – 8769 2100 Fax : 03 – 8926 2900 URL : www.niosh.com.my

CERTIFICATE OF TESTING

Reference No.	03-14B/02/2020/32/03-1
Client Company	Xfyre (M) Sdn Bhd
Client Company Address	No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor.
Test Item	Filtering Face Piece (FFP)
Brand/Model	Theracom Safemask N95
Lot/Batch/Production No.	-
Quantity	21
Date of Sample(s) Received	24th August 2020
Date (s) of Testing	24-27th August 2020
Test Specification	See page 2
Testing Laboratory	Dust Mask Laboratory (DML), NIOSH Malaysia

PREPARED BY : (Haalah binti Mahmud) DATE : 27/8/2020

APPROVED BY : (Baderin bin Osman) DATE : 27/8/2020

BADERIN BIN OSMAN
TECHNICAL EXPERT (T10)
CONSULTATION, RESEARCH & DEVELOPMENT DEPARTMENT
NIOSH

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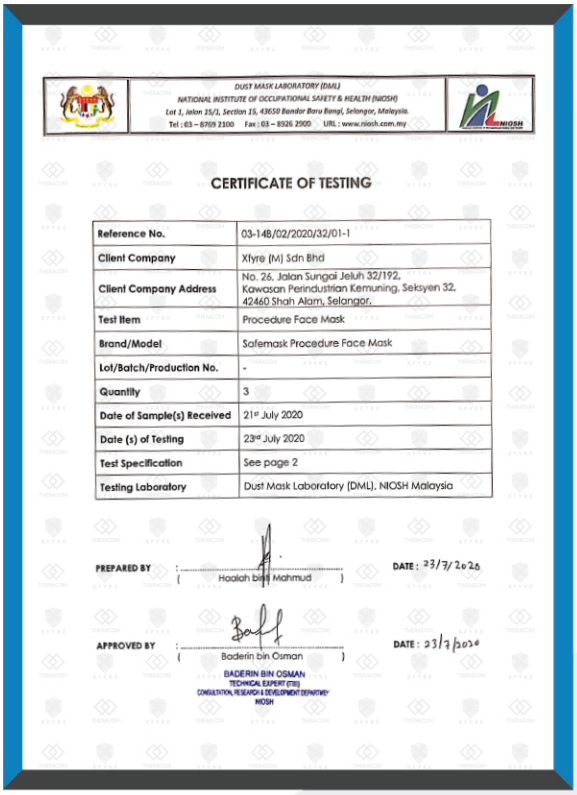

DUST MASK LABORATORY (DML)
NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY & HEALTH (NIOSH)
Lot 1, Jalan 15/1, Section 15, 43650 Bandar Baru Bangi, Selangor, Malaysia.
Tel : 03 – 8769 2100 Fax : 03 – 8926 2900 URL : www.niosh.com.my

CERTIFICATE OF TESTING

Reference No.	03-148/02/2020/32/01-1
Client Company	Xfyre (M) Sdn Bhd
Client Company Address	No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor.
Test Item	Procedure Face Mask
Brand/Model	Safemask Procedure Face Mask
Lot/Batch/Production No.	-
Quantity	3
Date of Sample(s) Received	21st July 2020
Date (s) of Testing	23rd July 2020
Test Specification	See page 2
Testing Laboratory	Dust Mask Laboratory (DML), NIOSH Malaysia

PREPARED BY : (Hoalah bin Mahmud) DATE : 23/7/2020

APPROVED BY : (Baderin bin Osman) DATE : 23/7/2020

BADERIN BIN OSMAN
TECHNICAL EXPERT (TEI)
CONSULTATION, RESEARCH & DEVELOPMENT DEPARTMENT
NIOSH

NIOSH

NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH

(FACE MASK)

Nelson Labs.
A Sotera Health company

NELSON LABS

(BACTERIAL FILTRATION EFFICIENCY)

CERTIFICATIONS

Nelson Labs.
A Sotera Health company

Sponsor:
Orissa Ismail
XFYRE (M) Sdn. Bhd.
No.26 Jalan Sungai Jeluh 32/192,
Seksyen 32
Shah Alam, Selangor, 42460
MALAYSIA

Bacterial Filtration Efficiency (BFE) Final Report

Test Article: THERACOM - SAFE MASK
Study Number: 1349934-S01
Study Received Date: 07 Oct 2020
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s): None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^8 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Inside
BFE Test Area: ~40 cm^2
BFE Flow Rate: 28.3 Liters per minute (L/min)
Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions: ~176 mm x ~150 mm
Positive Control Average: 3.0 x 10^8 CFU
Negative Monitor Count: <1 CFU
MPS: 2.9 µm

Sean Shepherd electronically approved for Study Director — James Luskin
09 Nov 2020 17:28 (+00:00) Study Completion Date and Time

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FRT0004-0001 Rev 22
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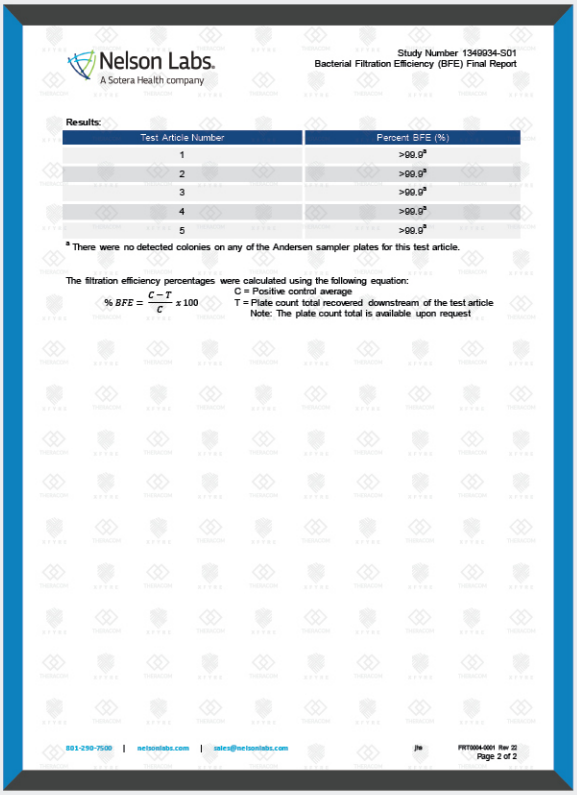

Nelson Labs.
A Sotera Health company

Study Number 1349934-S01
Bacterial Filtration Efficiency (BFE) Final Report

Results:

Test Article Number	Percent BFE (%)
1	>99.9[a]
2	>99.9[a]
3	>99.9[a]
4	>99.9[a]
5	>99.9[a]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} \times 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

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FRT0004-0001 Rev 22
Page 2 of 2

EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

(SAFE MASK PRECEDURE EARLOOP FACE MASK)

(SAFE GLOVE LATEX DISPOSABLE GLOVE)

(SAFE GLOVE NITRILE DISPOSABLE GLOVE)

CERTIFICATIONS

Obelis EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

E.A.R.-CERTIFICATE

(ARTICLE 14.2 OF THE DIRECTIVE 93/42/EEC ON MEDICAL DEVICES)

REF. NO.: AF 0588-2021

ORDER NO.: YA 0052-2020 N

DATE: 14/01/2021

MANUFACTURER: XFYRE (M) SDN. BHD. No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor Darul Ehsan, Malaysia

FACILITIES: XFYRE (M) SDN. BHD. No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor Darul Ehsan, Malaysia

PRODUCT CATEGORIES: Please See Annex A - List of Devices (3 Devices, 1 Page)

MODELS: Please See Annex A - List of Devices (3 Devices, 1 Page)

The European Authorized Representative Center Obelis s.a. declares that the aforementioned manufacturer has fulfilled the essential requirement of appointing a European Authorized Representative in accordance with article 14.2 of the MDD 93/42/EEC and to the terms and conditions set out in the agreement entered into force on 1st October 2020.*

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

*This certificate is not a confirmation of product notification nor an approval to place products on the market.
**This certificate will become void automatically upon termination of the EAR agreement.

Registered Address : Bd. Général Wahis 53 - 1030 Brussels I Registered Office Address : Bd Brand Whitlock 39, B-1200 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net I Website: www.obelis.net
V3 – ID: 00453416 – 22/02/2019

Order No.: YA 0052-2020N
Ref No.: AF 0588-2021

Annex A - List of Devices

(Article 9, section 1 of the Directive 93/42/EEC on medical devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN	Class	Rule
1.	910306-A	SAFEMASK Procedure Earloop Face Mask	4ply Disposable Face Mask	Procedure Earloop Face Mask is 4-ply surgical mask that to be used as a barrier to prevent air borne transfer of bacteria and particles, and it offers filtration efficient, fluid-resistant, superior comfort and breath ability to help reduce wearer to exposure of potentially infectious particles, blood and body fluids. It is designed to be use in hospital, clinic, operating theater and clean room environment, etc.	35177	I	1
2.	910312 - xs/s/m/l/xl	SAFEGLOVES Latex Disposable Gloves	Latex Disposable Glove	Latex Disposable Gloves is intended as a protective barrier when worn on the hands of healthcare providers during patient examination/treatment or for other sanitary purposes; its inner surface is not covered with powder and it does not include antimicrobial agents/materials.	47172	I	5
3.	910311 - xs/s/m/l/xl	SAFEGLOVES Nitrile Disposable Gloves	Nitrile Disposable Glove	Nitrile Disposable Gloves is intended as a protective barrier when worn on the hands of healthcare providers during patient examination/treatment or for other sanitary purposes; its inner surface is not covered with powder and it does not include antimicrobial agents/materials.	56286	I	5

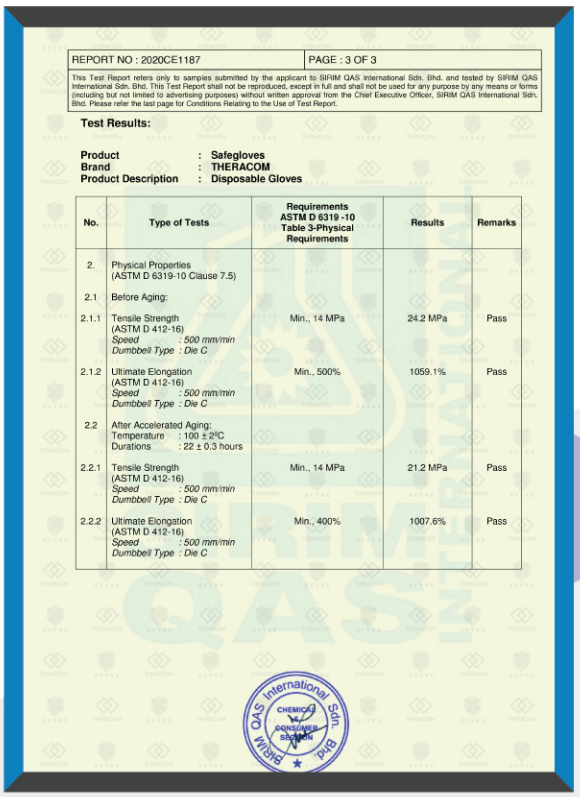
* Annex A is part of the Agreement.
** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (MDD 93/42/EEC, article 2 & Annex IX, MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)
*** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

Obelis s.a.

Signature:

Stamp:

G. ELKAYAM C.E.O
Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03



REPORT NO : 2020CE1187	PAGE : 3 OF 3

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Test Results:

Product : Safegloves
Brand : THERACOM
Product Description : Disposable Gloves

No.	Type of Tests	Requirements ASTM D 6319 -10 Table 3-Physical Requirements	Results	Remarks
2.	Physical Properties (ASTM D 6319-10 Clause 7.5)			
2.1	Before Aging:			
2.1.1	Tensile Strength (ASTM D 412-16) *Speed : 500 mm/min* *Dumbbell Type : Die C*	Min., 14 MPa	24.2 MPa	Pass
2.1.2	Ultimate Elongation (ASTM D 412-16) *Speed : 500 mm/min* *Dumbbell Type : Die C*	Min., 500%	1059.1%	Pass
2.2	After Accelerated Aging: Temperature : 100 ± 2°C Durations : 22 ± 0.3 hours			
2.2.1	Tensile Strength (ASTM D 412-16) *Speed : 500 mm/min* *Dumbbell Type : Die C*	Min., 14 MPa	21.2 MPa	Pass
2.2.2	Ultimate Elongation (ASTM D 412-16) *Speed : 500 mm/min* *Dumbbell Type : Die C*	Min., 400%	1007.6%	Pass

SIRIM QAS International Sdn Bhd CHEMICAL CONSUMER SECTION

EN 374

STANDARD FOR CHEMICAL SAFETY GLOVES

(EN374-1)

CERTIFICATIONS

REPORT NO : 2020CE1265 | PAGE : 4 OF 6

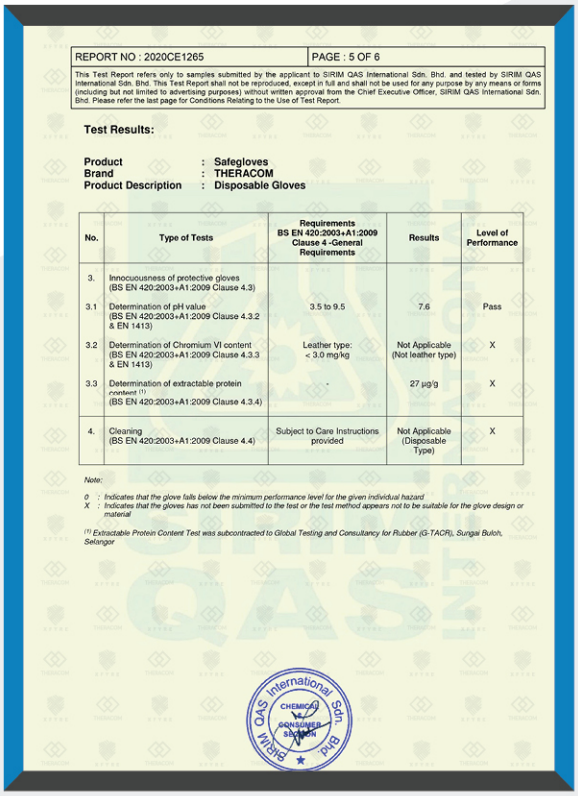
Test Results:

Product : Safegloves
Brand : THERACOM
Product Description : Disposable Gloves

No.	Type of Tests	Requirements BS EN 420:2003+A1:2009 Clause 4 -General Requirements	Results	Level of Performance
1.	Glove Design and Construction - General (BS EN 420:2003+A1:2009 Clause 4.1)	The protective glove shall be designed and manufactured so that in the foreseeable conditions of use for which it is intended , the user can perform related activity normally whilst enjoying appropriate protection at the highest level When the glove construction include seams, the material and strength of the seams shall be such that the overall performance of the glove is not significantly decreased.	The protective glove was designed and manufactured so that in the foreseeable conditions of use for which it is intended , the user can perform related activity normally whilst enjoying appropriate protection at the highest level The material strength for overall performance of the glove was not significantly decreased (Measured Material Strength: 13.8 Mpa)	Pass Pass
2.	Resistance of glove materials to water penetration (BS EN 420:2003+A1:2009 Clause 4.2)	For leather gloves: Time penetration Level 1 : 30 mins Level 2 : 60 mins Level 3 : 120 mins Level 4 : 180 mins For textile materials: To be reported based on method in EN 20811	Not Applicable	X

Note:

0 : Indicates that the glove falls below the minimum performance level for the given individual hazard
X : Indicates that the gloves has not been submitted to the test or the test method appears not to be suitable for the glove design or material



REPORT NO : 2020CE1265 | PAGE : 5 OF 6

Test Results:

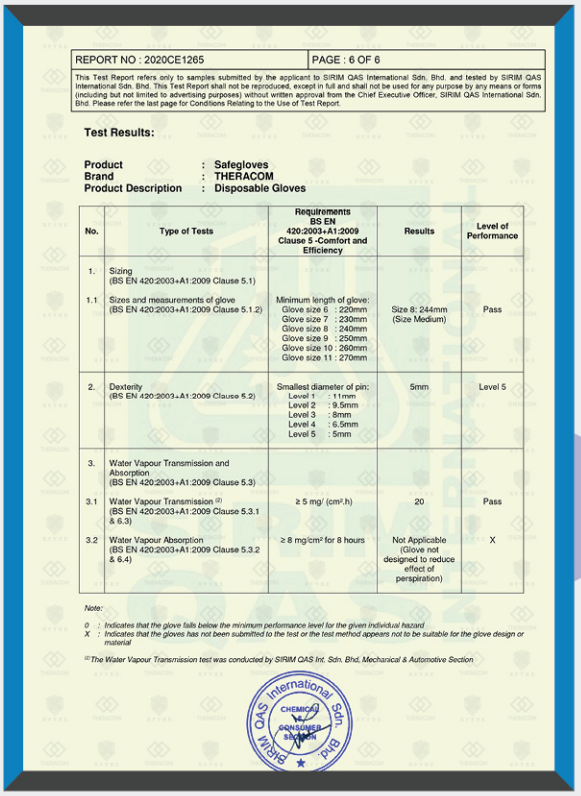
Product : Safegloves
Brand : THERACOM
Product Description : Disposable Gloves

No.	Type of Tests	Requirements BS EN 420:2003+A1:2009 Clause 4 -General Requirements	Results	Level of Performance
3.	Innocuousness of protective gloves (BS EN 420:2003+A1:2009 Clause 4.3)			
3.1	Determination of pH value (BS EN 420:2003+A1:2009 Clause 4.3.2 & EN 1413)	3.5 to 9.5	7.6	Pass
3.2	Determination of Chromium VI content (BS EN 420:2003+A1:2009 Clause 4.3.3 & EN 1413)	Leather type: < 3.0 mg/kg	Not Applicable (Not leather type)	X
3.3	Determination of extractable protein content [1] (BS EN 420:2003+A1:2009 Clause 4.3.4)	-	27 µg/g	X
4.	Cleaning (BS EN 420:2003+A1:2009 Clause 4.4)	Subject to Care Instructions provided	Not Applicable (Disposable Type)	X

Note:

0 : Indicates that the glove falls below the minimum performance level for the given individual hazard
X : Indicates that the gloves has not been submitted to the test or the test method appears not to be suitable for the glove design or material

[1] Extractable Protein Content Test was subcontracted to Global Testing and Consultancy for Rubber (G-TACR), Sungai Buloh, Selangor



REPORT NO : 2020CE1265 | PAGE : 6 OF 6

Test Results:

Product : Safegloves
Brand : THERACOM
Product Description : Disposable Gloves

No.	Type of Tests	Requirements BS EN 420:2003+A1:2009 Clause 5 -Comfort and Efficiency	Results	Level of Performance
1.	Sizing (BS EN 420:2003+A1:2009 Clause 5.1)			
1.1	Sizes and measurements of glove (BS EN 420:2003+A1:2009 Clause 5.1.2)	Minimum length of glove: Glove size 6 : 220mm Glove size 7 : 230mm Glove size 8 : 240mm Glove size 9 : 250mm Glove size 10 : 260mm Glove size 11 : 270mm	Size 8: 244mm (Size Medium)	Pass
2.	Dexterity (BS EN 420:2003+A1:2009 Clause 5.2)	Smallest diameter of pin: Level 1 : 11mm Level 2 : 9.5mm Level 3 : 8mm Level 4 : 6.5mm Level 5 : 5mm	5mm	Level 5
3.	Water Vapour Transmission and Absorption (BS EN 420:2003+A1:2009 Clause 5.3)			
3.1	Water Vapour Transmission [2] (BS EN 420:2003+A1:2009 Clause 5.3.1 & 6.3)	≥ 5 mg/ (cm².h)	20	Pass
3.2	Water Vapour Absorption (BS EN 420:2003+A1:2009 Clause 5.3.2 & 6.4)	≥ 8 mg/cm² for 8 hours	Not Applicable (Glove not designed to reduce effect of perspiration)	X

Note:

0 : Indicates that the glove falls below the minimum performance level for the given individual hazard
X : Indicates that the gloves has not been submitted to the test or the test method appears not to be suitable for the glove design or material

[2] The Water Vapour Transmission test was conducted by SIRIM QAS Int. Sdn. Bhd, Mechanical & Automotive Section

EN 374

STANDARD FOR CHEMICAL SAFETY GLOVES

(EN374-5 : PENETRATION BY BLOOD-BORNE)

CERTIFICATIONS

SIRIM Berhad
Industrial Biotechnology Research Centre, Building 19
Tel: 03-55446953/6960
Fax: 03-55446988

TEST REPORT

REPORT NO: R1307 /20/B19/91	PAGE: 1 of 2

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Applicant	:	Orissa
Company	:	XFYRE (M) SDN. BHD.
Address	:	No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor Darul Ehsan, MALAYSIA.
Manufacturer	:	Not stated
Address	:	Not stated
Sample	:	Disposable glove
Reference standard / Method of Test	:	Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X174 bacteriophage. ISO 16604:2004(E).
Sample description	:	Received one (1) sample with the following identification for testing:

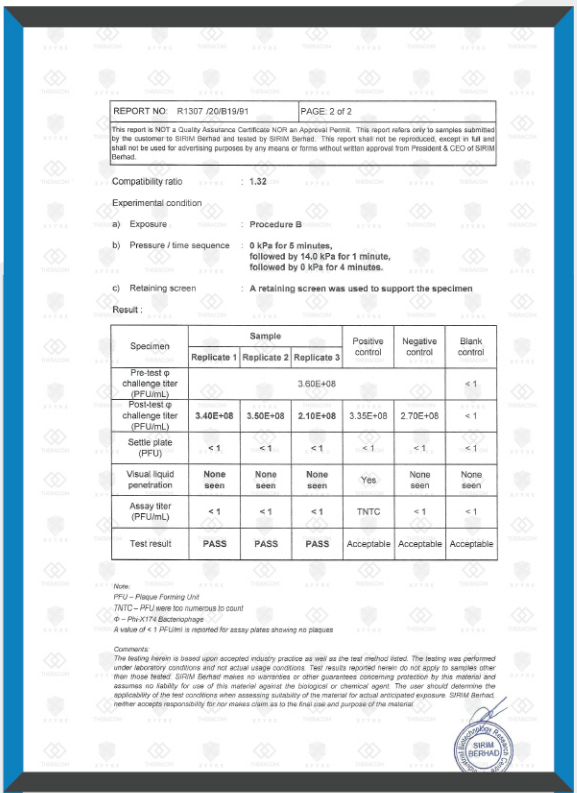
No.	Sample marking	Brand	Size	Quantity
1.	THERACOM - SAFEGLOVES	Nitrile disposable glove	Not stated	3 pairs

Date received	:	3 November, 2020
Date test started	:	9 November, 2020
Job No.	:	J 1307
Issue date	:	16 November, 2020

Approved signatories,

(MOHD KHAIRUL AZWAN AHMAD)
MJMM 0481
Analyst,
Industrial Biotechnology Research Centre,
SIRIM Berhad

(MOHD MAHAYUDDIN HUSSIN)
MJMM 0482
Reviewer,
Industrial Biotechnology Research Centre,
SIRIM Berhad



REPORT NO: R1307 /20/B19/91	PAGE: 2 of 2

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Compatibility ratio : 1.32

Experimental condition

a) Exposure : Procedure B

b) Pressure / time sequence : 0 kPa for 5 minutes, followed by 14.0 kPa for 1 minute, followed by 0 kPa for 4 minutes.

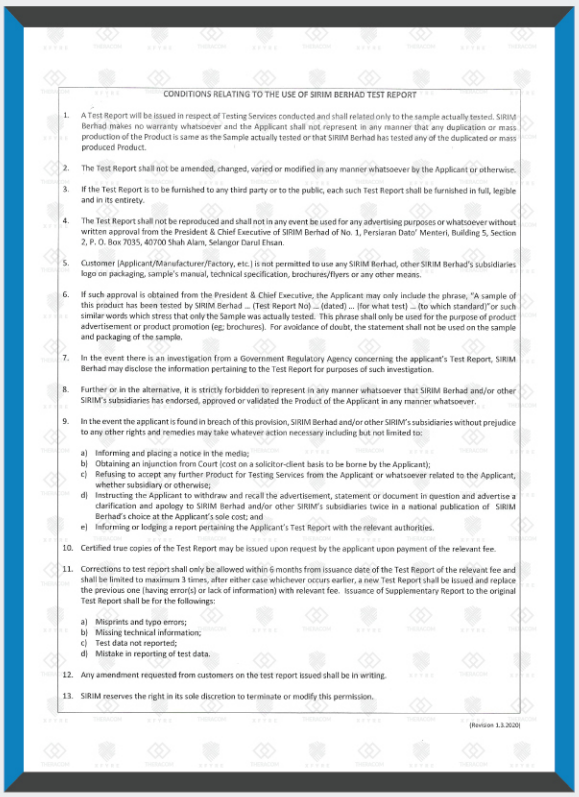
c) Retaining screen : A retaining screen was used to support the specimen

Result :

Specimen	Sample			Positive control	Negative control	Blank control
	Replicate 1	Replicate 2	Replicate 3			
Pre-test φ challenge titer (PFU/mL)	3.60E+08					< 1
Post-test φ challenge titer (PFU/mL)	3.40E+08	3.50E+08	2.10E+08	3.35E+08	2.70E+08	< 1
Settle plate (PFU)	< 1	< 1	< 1	< 1	< 1	< 1
Visual liquid penetration	None seen	None seen	None seen	Yes	None seen	None seen
Assay titer (PFU/mL)	< 1	< 1	< 1	TNTC	< 1	< 1
Test result	PASS	PASS	PASS	Acceptable	Acceptable	Acceptable

Note:
PFU – Plaque Forming Unit
TNTC – PFU were too numerous to count
φ – Phi-X174 Bacteriophage
A value of < 1 PFU/ml is reported for assay plates showing no plaques

Comments:
The testing herein is based upon accepted industry practice as well as the test method listed. The testing was performed under laboratory conditions and not actual usage conditions. Test results reported herein do not apply to samples other than those tested. SIRIM Berhad makes no warranties or other guarantees concerning protection by this material and assumes no liability for use of this material against the biological or chemical agent. The user should determine the applicability of the test conditions when assessing suitability of the material for actual anticipated exposure. SIRIM Berhad neither accepts responsibility for nor makes claim as to the final use and purpose of the material.



CONDITIONS RELATING TO THE USE OF SIRIM BERHAD TEST REPORT

1. A Test Report will be issued in respect of Testing Services conducted and shall related only to the sample actually tested. SIRIM Berhad makes no warranty whatsoever and the Applicant shall not represent in any manner that any duplication or mass production of the Product is same as the Sample actually tested or that SIRIM Berhad has tested any of the duplicated or mass produced Product.
2. The Test Report shall not be amended, changed, varied or modified in any manner whatsoever by the Applicant or otherwise.
3. If the Test Report is to be furnished to any third party or to the public, each such Test Report shall be furnished in full, legible and in its entirety.
4. The Test Report shall not be reproduced and shall not in any event be used for any advertising purposes or whatsoever without written approval from the President & Chief Executive of SIRIM Berhad of No. 1, Persiaran Dato' Menteri, Building 5, Section 2, P. O. Box 7035, 40700 Shah Alam, Selangor Darul Ehsan.
5. Customer (Applicant/Manufacturer/Factory, etc.) is not permitted to use any SIRIM Berhad, other SIRIM Berhad's subsidiaries logo on packaging, sample's manual, technical specification, brochures/flyers or any other means.
6. If such approval is obtained from the President & Chief Executive, the Applicant may only include the phrase, "A sample of this product has been tested by SIRIM Berhad ... (Test Report No) ... (dated) ... (for what test) ... (to which standard)" or such similar words which stress that only the Sample was actually tested. This phrase shall only be used for the purpose of product advertisement or product promotion (eg; brochures). For avoidance of doubt, the statement shall not be used on the sample and packaging of the sample.
7. In the event there is an investigation from a Government Regulatory Agency concerning the applicant's Test Report, SIRIM Berhad may disclose the information pertaining to the Test Report for purposes of such investigation.
8. Further or in the alternative, it is strictly forbidden to represent in any manner whatsoever that SIRIM Berhad and/or other SIRIM's subsidiaries has endorsed, approved or validated the Product of the Applicant in any manner whatsoever.
9. In the event the applicant is found in breach of this provision, SIRIM Berhad and/or other SIRIM's subsidiaries without prejudice to any other rights and remedies may take whatever action necessary including but not limited to:
   a) Informing and placing a notice in the media;
   b) Obtaining an injunction from Court (cost on a solicitor-client basis to be borne by the Applicant);
   c) Refusing to accept any further Product for Testing Services from the Applicant or whatsoever related to the Applicant, whether subsidiary or otherwise;
   d) Instructing the Applicant to withdraw and recall the advertisement, statement or document in question and advertise a clarification and apology to SIRIM Berhad and/or other SIRIM's subsidiaries twice in a national publication of SIRIM Berhad's choice at the Applicant's sole cost; and
   e) Informing or lodging a report pertaining the Applicant's Test Report with the relevant authorities.
10. Certified true copies of the Test Report may be issued upon request by the applicant upon payment of the relevant fee.
11. Corrections to test report shall only be allowed within 6 months from issuance date of the Test Report of the relevant fee and shall be limited to maximum 3 times, after either case whichever occurs earlier, a new Test Report shall be issued and replace the previous one (having error(s) or lack of information) with relevant fee. Issuance of Supplementary Report to the original Test Report shall be for the followings:
    a) Misprints and typo errors;
    b) Missing technical information;
    c) Test data not reported;
    d) Mistake in reporting of test data.
12. Any amendment requested from customers on the test report issued shall be in writing.
13. SIRIM reserves the right in its sole discretion to terminate or modify this permission.

(Revision 1.3.2020)

SIRIM QAS INTERNATIONAL

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Fax: 03-55446688
www.sirim-qas.com.my

TEST REPORT

REPORT NO : 2020CE1265	PAGE : 1 OF 6

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Applicant	: XFYRE (M) SDN. BHD., No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor Darul Ehsan, Malaysia
Manufacturer	: Not Stated
Product	: Safegloves
Reference Standard / Method of Test	: BS EN ISO 374-1:2016+A1:2018 – Title: Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
Description of sample	: Received one (1) sample of Safegloves for testing which was identified as: Brand: THERACOM Product Description: Disposable Gloves
Date Received of Complete Application	: 30 July 2020
Job No.	: J20201400855
Description of Test Results	: This test report covers only test clauses as requested by Applicant to SIRIM QAS International Sdn. Bhd. The test results for the submitted test sample as described in this test report complied with the requirement of the above reference standard at the respective clauses tested
Issued Date	: 02 December 2020

Approved Signatory;

(MUHAMMAD RIZAL BIN ABDUL RAHIM)
Senior Testing Executive

SIRIM QAS International Sdn Bhd CHEMICAL & CONSUMER SECTION

(HAHNAS BINTI MAHBUT)
Head
Chemical & Consumer Section
Testing Services Department

EN 374

STANDARD FOR CHEMICAL SAFETY GLOVES

(EN374-1)

CERTIFICATIONS

REPORT NO : 2020CE1265	PAGE : 2 OF 6

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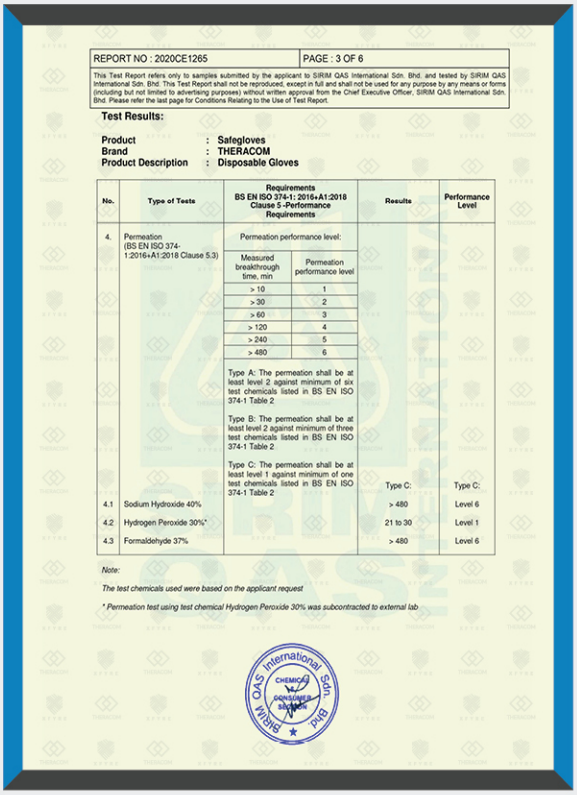
Test Results:

Product : Safegloves
Brand : THERACOM
Product Description : Disposable Gloves

No.	Type of Tests	Requirements BS EN ISO 374-1: 2016+A1:2018 Clause 5 -Performance Requirements	Results	Remarks
1.	General Requirements (BS EN ISO 374-1:2016+A1:2018 Clause 5.1)	Protective gloves against dangerous chemicals shall comply with the requirements given in EN 420:2009 Clause 4, Clause 5 and Clause 7	Please refer page 4 to 6	-
2.	Penetration (BS EN ISO 374-1:2016+A1:2018 Clause 5.2)	Protective gloves shall not leak when tested according to EN 374-2:2014 Clause 7.2, 7.3		
2.1	Air Leak Test (BS EN ISO 374-2:2019 Clause 7.2)		There was no emergence of air bubbles observed on the tested gloves	Pass
2.2	Water Leak Test (BS EN ISO 374-2:2019 Clause 7.3)		There were no water leaks observed on the tested gloves	Pass
3.	Degradation (BS EN ISO 374-1:2016+A1:2018 Clause 5.3)	The degradation (DR) shall be determined according to EN 374-4 for each chemical claimed in the marking and reported in the user instruction	There was no resistance to degradation by chemicals claimed in the marking and user instruction	-

SIRIM QAS International Sdn Bhd CHEMICAL & CONSUMER SECTION



REPORT NO : 2020CE1265	PAGE : 3 OF 6

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Test Results:

Product : Safegloves
Brand : THERACOM
Product Description : Disposable Gloves

No.	Type of Tests	Requirements BS EN ISO 374-1: 2016+A1:2018 Clause 5 -Performance Requirements	Results	Performance Level
4.	Permeation (BS EN ISO 374-1:2016+A1:2018 Clause 5.3)	Permeation performance level: Measured breakthrough time, min / Permeation performance level > 10 / 1 > 30 / 2 > 60 / 3 > 120 / 4 > 240 / 5 > 480 / 6 Type A: The permeation shall be at least level 2 against minimum of six test chemicals listed in BS EN ISO 374-1 Table 2 Type B: The permeation shall be at least level 2 against minimum of three test chemicals listed in BS EN ISO 374-1 Table 2 Type C: The permeation shall be at least level 1 against minimum of one test chemicals listed in BS EN ISO 374-1 Table 2	Type C:	Type C:
4.1	Sodium Hydroxide 40%		> 480	Level 6
4.2	Hydrogen Peroxide 30%*		21 to 30	Level 1
4.3	Formaldehyde 37%		> 480	Level 6

Note:

The test chemicals used were based on the applicant request

** Permeation test using test chemical Hydrogen Peroxide 30% was subcontracted to external lab*

SIRIM QAS International Sdn Bhd CHEMICAL & CONSUMER SECTION

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TEST REPORT

REPORT NO.: 2020PC0936	PAGE : 1 OF 3

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Applicant	:	XFYRE (M) SDN BHD No. 26 Jalan Sungai Jeluh 32/192 Kawasan Perindustrian Kemuning, Seksyen 32 40460 Shah Alam Selangor
Manufacturer	:	-same as above-
Product	:	THERACOM SAFEGLOVES - NITRILE GLOVES
Reference Standard/ Method of Test	:	1) BS EN ISO 374-5: 2016 – Protective Gloves Against Dangerous Chemicals and Micro-Organisms Part 5: Terminology and Performance Requirements for Micro-Organisms Risks (ISO 374-5: 2016) 2) EN ISO 374-2: 2019 – Protective Gloves Against Dangerous Chemicals and Micro-Organisms Part 2: Determination of Resistance to Penetration
Description of Sample	:	One (1) box of new glove sample was received on 9 November 2020. Photograph of the glove sample is shown in Figure 1 in Page 2 of this report.
Date Received of Complete Application	:	9 November 2020
Job No.	:	J20201460649
Description of Test Results	:	This test report covers only test clauses as requested by Applicant of SIRIM QAS International Sdn. Bhd. The test results for the submitted test sample as described in this test report complied with the requirements of the above reference standards at the respective clauses tested.
Issued Date	:	13 November 2020

Approved Signatories:

(Rosli Ahad)
Testing Executive

SIRIM QAS International Sdn. Bhd. PLASTICS & COMPOSITE MATERIALS SECTION

(Rahmad Abd Shukor)
Head
Plastics and Composite Materials Section
Testing Services Department

EN 374

STANDARD FOR CHEMICAL SAFETY GLOVES

(EN374-5 : PENETRATION AGAINST VIRUS)

CERTIFICATIONS

REPORT NO.: 2020PC0936	PAGE : 2 OF 3

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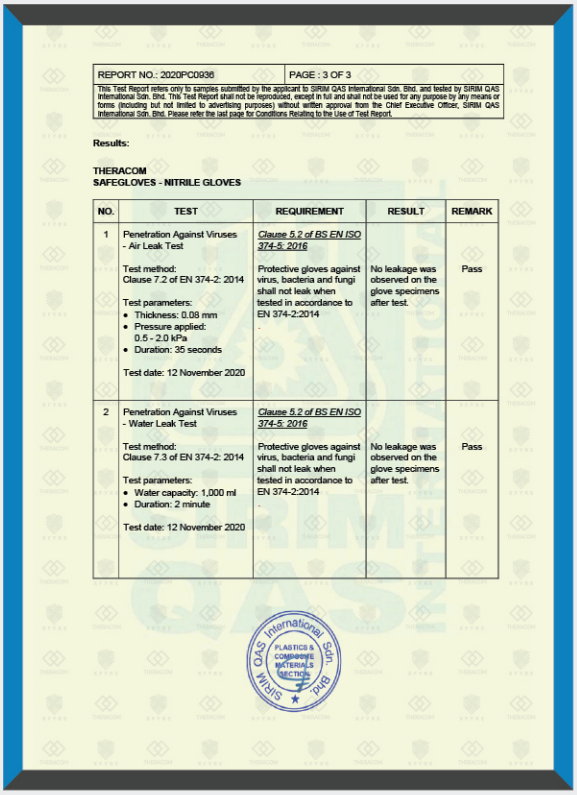
Description of Sample:

Figure 1. Photograph of 'THERACOM; SAFEGLOVES - NITRILE GLOVES' Sample

SIRIM QAS International Sdn. Bhd. PLASTICS & COMPOSITE MATERIALS SECTION



REPORT NO.: 2020PC0936	PAGE : 3 OF 3

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Results:

THERACOM
SAFEGLOVES - NITRILE GLOVES

NO.	TEST	REQUIREMENT	RESULT	REMARK
1	Penetration Against Viruses - Air Leak Test Test method: Clause 7.2 of EN 374-2: 2014 Test parameters: • Thickness: 0.08 mm • Pressure applied: 0.5 - 2.0 kPa • Duration: 35 seconds Test date: 12 November 2020	*Clause 5.2 of BS EN ISO 374-5: 2016* Protective gloves against virus, bacteria and fungi shall not leak when tested in accordance to EN 374-2:2014	No leakage was observed on the glove specimens after test.	Pass
2	Penetration Against Viruses - Water Leak Test Test method: Clause 7.3 of EN 374-2: 2014 Test parameters: • Water capacity: 1,000 ml • Duration: 2 minute Test date: 12 November 2020	*Clause 5.2 of BS EN ISO 374-5: 2016* Protective gloves against virus, bacteria and fungi shall not leak when tested in accordance to EN 374-2:2014	No leakage was observed on the glove specimens after test.	Pass

SIRIM QAS International Sdn. Bhd. PLASTICS & COMPOSITE MATERIALS SECTION

SIRIM QAS INTERNATIONAL

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40700 Shah Alam, Selangor Darul Ehsan, Malaysia
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TEST REPORT

REPORT NO : 2020CE1264	PAGE : 1 OF 4

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Applicant	: XFYRE (M) SDN. BHD., No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor Darul Ehsan, Malaysia
Manufacturer	: Not Stated
Product	: Safegloves
Reference Standard / Method of Test	: BS EN 420:2003+A1:2009 – Title: Protective gloves. General requirements and test methods
Description of sample	: Received one (1) sample of Safegloves for testing which was identified as: Brand: THERACOM Product Description: Disposable Gloves
Date Received of Complete Application	: 30 July 2020
Job No.	: J20201400855
Description of Test Results	: This test report covers only test clauses as requested by Applicant to SIRIM QAS International Sdn. Bhd. The test results for the submitted test sample as described in this test report complied with the requirement of the above reference standard at the respective clauses tested
Issued Date	: 28 September 2020

Approved Signatory;

(MUHAMMAD RIZAL BIN ABDUL RAHIM)
Senior Testing Executive

SIRIM QAS International Sdn Bhd CHEMICAL & CONSUMER SECTION

(HAHNAS BINTI MAHBUT)
Head
Chemical & Consumer Section
Testing Services Department

EN 420

STANDARD FOR CHEMICAL SAFETY GLOVES

(EN420)

CERTIFICATIONS

REPORT NO : 2020CE1264	PAGE : 2 OF 4

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Test Results:

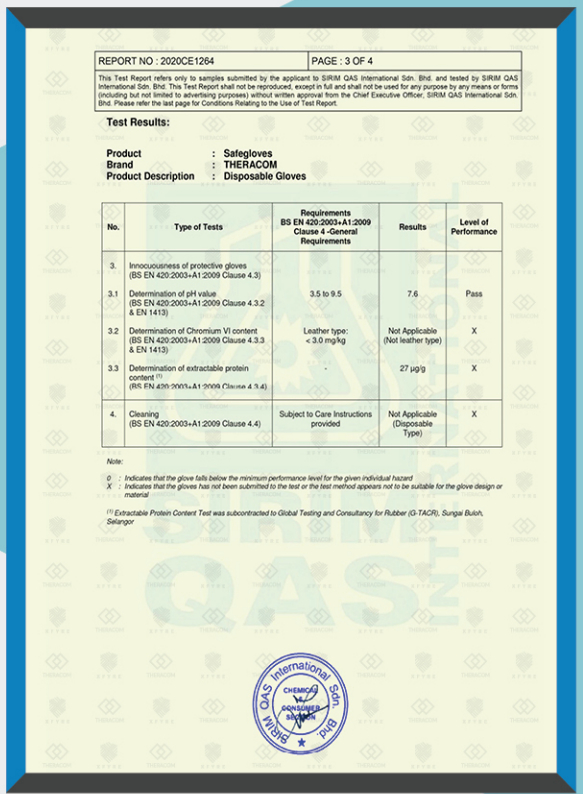
Product : Safegloves
Brand : THERACOM
Product Description : Disposable Gloves

No.	Type of Tests	Requirements BS EN 420:2003+A1:2009 Clause 4 -General Requirements	Results	Level of Performance
1.	Glove Design and Construction - General (BS EN 420:2003+A1:2009 Clause 4.1)	The protective glove shall be designed and manufactured so that in the foreseeable conditions of use for which it is intended , the user can perform related activity normally whilst enjoying appropriate protection at the highest level When the glove construction include seams, the material and strength of the seams shall be such that the overall performance of the glove is not significantly decreased.	The protective glove was designed and manufactured so that in the foreseeable conditions of use for which it is intended , the user can perform related activity normally whilst enjoying appropriate protection at the highest level The material strength for overall performance of the glove was not significantly decreased (Measured Material Strength: 13.8 Mpa)	Pass Pass
2.	Resistance of glove materials to water penetration (BS EN 420:2003+A1:2009 Clause 4.2)	For leather gloves: Time penetration Level 1 : 30 mins Level 2 : 60 mins Level 3 : 120 mins Level 4 : 180 mins For textile materials: To be reported based on method in EN 20811	Not Applicable	X

Note:

0 : Indicates that the glove falls below the minimum performance level for the given individual hazard
X : Indicates that the gloves has not been submitted to the test or the test method appears not to be suitable for the glove design or material

SIRIM QAS International Sdn Bhd CHEMICAL & CONSUMER SECTION



REPORT NO : 2020CE1264	PAGE : 3 OF 4

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Test Results:

Product : Safegloves
Brand : THERACOM
Product Description : Disposable Gloves

No.	Type of Tests	Requirements BS EN 420:2003+A1:2009 Clause 4 -General Requirements	Results	Level of Performance
3.	Innocuousness of protective gloves (BS EN 420:2003+A1:2009 Clause 4.3)			
3.1	Determination of pH value (BS EN 420:2003+A1:2009 Clause 4.3.2 & EN 1413)	3.5 to 9.5	7.6	Pass
3.2	Determination of Chromium VI content (BS EN 420:2003+A1:2009 Clause 4.3.3 & EN 1413)	Leather type: < 3.0 mg/kg	Not Applicable (Not leather type)	X
3.3	Determination of extractable protein content [1] (BS EN 420:2003+A1:2009 Clause 4.3.4)	-	27 µg/g	X
4.	Cleaning (BS EN 420:2003+A1:2009 Clause 4.4)	Subject to Care Instructions provided	Not Applicable (Disposable Type)	X

Note:

0 : Indicates that the glove falls below the minimum performance level for the given individual hazard
X : Indicates that the gloves has not been submitted to the test or the test method appears not to be suitable for the glove design or material

[1] Extractable Protein Content Test was subcontracted to Global Testing and Consultancy for Rubber (G-TACR), Sungai Buloh, Selangor

SIRIM QAS International Sdn Bhd CHEMICAL & CONSUMER SECTION

CE
EN455

CE MARK 455-1

(MADE IN COMPLIANCE WITH 93/42/EEC)

(EN455-1)

CERTIFICATIONS

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No.1, Persiaran Dato' Menteri, P.O.BOX 7035, Section 2,
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TEST REPORT

REPORT NO : 2020CE1000	PAGE : 1 OF 2

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Applicant	: XFYRE (M) SDN. BHD., No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor Darul Ehsan, Malaysia
Manufacturer	: Not Stated
Product	: Safegloves
Reference Standard / Method of Test	: BS EN 455-1:2000 – Title: Medical gloves for single use - Requirements and testing for freedom from holes
Description of sample	: Received one (1) sample of Safegloves for testing which was identified as: Brand: THERACOM Product Description: Disposable Gloves
Date Received of Complete Application	: 30 July 2020
Job No.	: J20201400857
Description of Test Results	: This test report covers only test clauses as requested by Applicant to SIRIM QAS International Sdn. Bhd. The test results for the submitted test sample as described in this test report complied with the requirement of the above reference standard at the respective clauses tested
Issued Date	: 18 August 2020

Approved Signatory;

(MUHAMMAD RIZAL BIN ABDULLAH (M))
Senior Testing Executive

(HAHNAS BINTI MAHBUT)
Head
Chemical & Consumer Section
Testing Services Department

SIRIM QAS International Sdn. Bhd. CHEMICAL & CONSUMER SECTION

REPORT NO : 2020CE1000	PAGE : 2 OF 2

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Test Results:

Product : Safegloves
Brand : THERACOM
Product Description : Disposable Gloves

No.	Type of Test	Requirement BS EN 455-1:2000 Clause 4	Result	Remark
1.	Watertightness test for detection of holes (EN 455-1:2000 Clause 5) *Test Conditions:* *Volume of Water : 1000 ml* *Water Temperature : 15 to 35ºC* *Duration : 3 minutes*	Medical gloves for single use shall not leak when tested in accordance with EN 455-1 Clause 5	Visual Inspection: No water leakage observed	Pass

SIRIM QAS International Sdn. Bhd. CHEMICAL & CONSUMER SECTION

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3. If the Test Report is to be furnished to any third party or to the public, each such Test Report shall be furnished in full, legible and in its entirety.
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   b) Obtaining an injunction from Court (cost on a solicitor-client basis to be borne by the Applicant);
   c) Refusing to accept any further Product for Testing Services from the Applicant or whosoever related to the Applicant, whether subsidiary or otherwise;
   d) Instructing the Applicant to withdraw and recall the advertisement, statement or document in question and advertise a clarification and apology to SIRIM QAS International, SIRIM and/or other SIRIM's subsidiaries twice in a national publication of SIRIM QAS International's choice at the Applicant's sole cost, and.
   e) Informing or lodging a report pertaining the Applicant's Test Report with the relevant authorities.
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    a) Changes in details of the Applicant name and/or address;
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    c) Changes in details of the Factory location name and/or address;
    d) Changes in details of the model and/or type designation
12. However, issuance of Supplementary Report due to the following reasons are FOC :
    a) Misprints and typo errors;
    b) Missing technical information as agreed in PP1 form;
    c) Test data not reported;
    d) Mistake in reporting of test data
13. Corrections to report shall only be allowed if the date of issuance of the original report has not exceeded 6 months and shall be limited to maximum 3 times, after either case whichever occurs earlier, an Amendment or a Supplementary Report shall not be issued.

SIRIM QAS INTERNATIONAL

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(Company No.: 199601027901 (410334-X))
No.1, Persiaran Dato' Menteri, P.O.BOX 7035, Section 2,
40700 Shah Alam, Selangor Darul Ehsan, Malaysia
Tel: 03-55445168
Fax: 03-55446688
www.sirim-qas.com.my

TEST REPORT

REPORT NO : 2020CE1000	PAGE : 1 OF 2

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THIS TEST REPORT IS ISSUED IN SECURED PDF SOFTCOPY

Applicant	: XFYRE (M) SDN. BHD., No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor Darul Ehsan, Malaysia
Manufacturer	: Not Stated
Product	: Safegloves
Reference Standard / Method of Test	: BS EN 455-1:2000 – Title: Medical gloves for single use - Requirements and testing for freedom from holes
Description of sample	: Received one (1) sample of Safegloves for testing which was identified as: Brand: THERACOM Product Description: Disposable Gloves
Date Received of Complete Application	: 30 July 2020
Job No.	: J20201400857
Description of Test Results	: This test report covers only test clauses as requested by Applicant to SIRIM QAS International Sdn. Bhd. The test results for the submitted test sample as described in this test report complied with the requirement of the above reference standard at the respective clauses tested
Issued Date	: 18 August 2020

Approved Signatory;

(MUHAMMAD RIZAL BIN ABDULLAH)
Senior Testing Executive

SIRIM QAS International Sdn Bhd CHEMICAL & CONSUMER SECTION

(HAHNAS BINTI MAHBUT)
Head
Chemical & Consumer Section
Testing Services Department

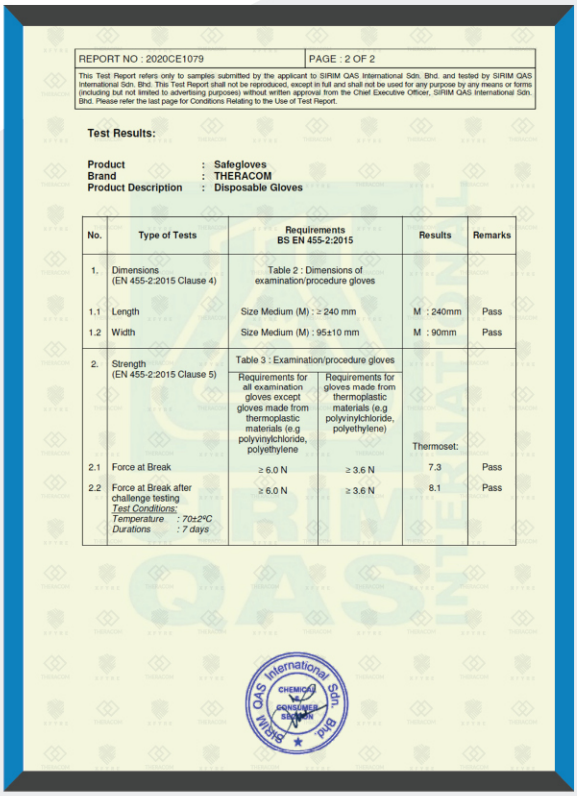
CE
EN455

CE MARK 455-2

(MADE IN COMPLIANCE WITH 93/42/EEC)

(EN455-1)

CERTIFICATIONS



REPORT NO : 2020CE1079	PAGE : 2 OF 2

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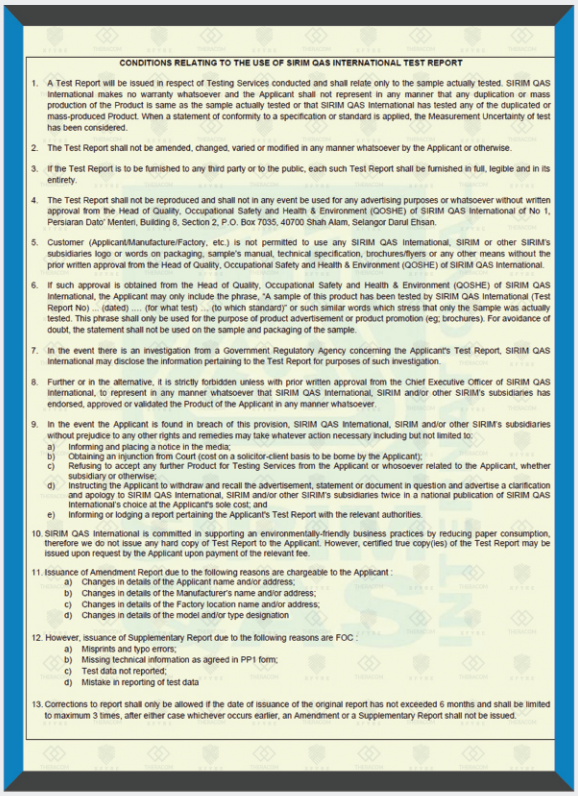
Test Results:

Product : Safegloves
Brand : THERACOM
Product Description : Disposable Gloves

No.	Type of Tests	Requirements BS EN 455-2:2015		Results	Remarks
1.	Dimensions (EN 455-2:2015 Clause 4)	Table 2 : Dimensions of examination/procedure gloves			
1.1	Length	Size Medium (M) : ≥ 240 mm		M : 240mm	Pass
1.2	Width	Size Medium (M) : 95±10 mm		M : 90mm	Pass
2.	Strength (EN 455-2:2015 Clause 5)	Table 3 : Examination/procedure gloves			
		Requirements for all examination gloves except gloves made from thermoplastic materials (e.g polyvinylchloride, polyethylene	Requirements for gloves made from thermoplastic materials (e.g polyvinylchloride, polyethylene)	Thermoset:	
2.1	Force at Break	≥ 6.0 N	≥ 3.6 N	7.3	Pass
2.2	Force at Break after challenge testing *Test Conditions:* *Temperature : 70±2°C* *Durations : 7 days*	≥ 6.0 N	≥ 3.6 N	8.1	Pass

SIRIM QAS International Sdn Bhd CHEMICAL & CONSUMER SECTION



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Certifications

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CE MARK 455-3 (CYTOTOXICITY)

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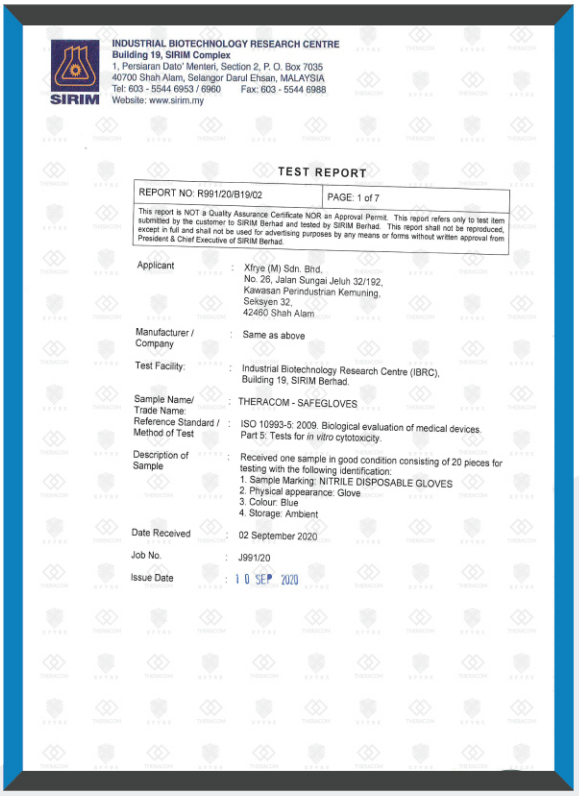

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TEST REPORT

REPORT NO: R991/20/B19/02 | PAGE: 1 of 7

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Applicant	:	Xfrye (M) Sdn. Bhd. No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam
Manufacturer / Company	:	Same as above
Test Facility:	:	Industrial Biotechnology Research Centre (IBRC), Building 19, SIRIM Berhad.
Sample Name/ Trade Name:	:	THERACOM - SAFEGLOVES
Reference Standard / Method of Test	:	ISO 10993-5: 2009. Biological evaluation of medical devices. Part 5: Tests for *in vitro* cytotoxicity.
Description of Sample	:	Received one sample in good condition consisting of 20 pieces for testing with the following identification: 1. Sample Marking: NITRILE DISPOSABLE GLOVES 2. Physical appearance: Glove 3. Colour: Blue 4. Storage: Ambient
Date Received	:	02 September 2020
Job No.	:	J991/20
Issue Date	:	10 SEP 2020

REPORT NO: R796/20/B19/02 | PAGE: 2 of 7

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APPROVED SIGNATORIES

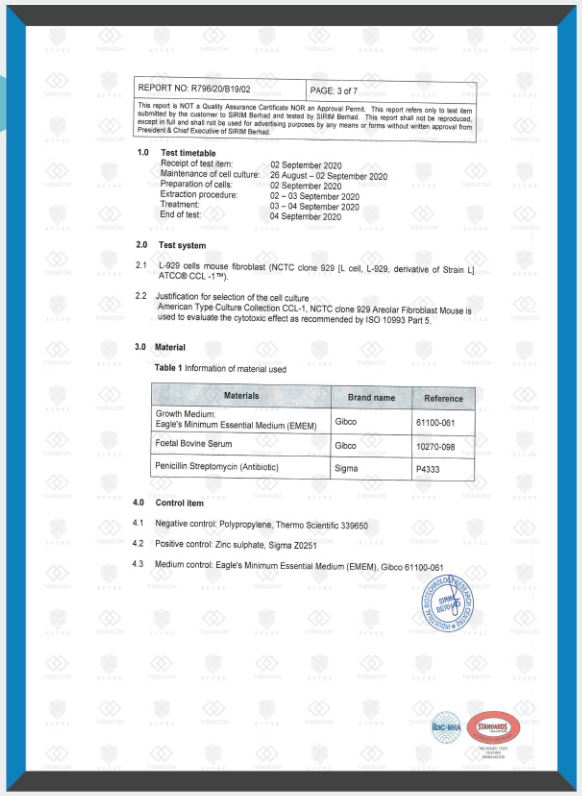
We, the undersigned, declare that the methods, results and data contained in this report faithfully reflect the procedures used and raw data collected throughout the testing.

(JUANI MAZMIN HUSIN)
Reviewer
Industrial Biotechnology Research Centre

10 SEP 2020
Date

(SYAMIMI MD KHALID)
Analyst
Industrial Biotechnology Research Centre

10 SEP 2020
Date



REPORT NO: R796/20/B19/02 | PAGE: 3 of 7

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1.0 Test timetable

Receipt of test item:	02 September 2020
Maintenance of cell culture:	26 August – 02 September 2020
Preparation of cells:	02 September 2020
Extraction procedure:	02 – 03 September 2020
Treatment:	03 – 04 September 2020
End of test:	04 September 2020

2.0 Test system

2.1 L-929 cells mouse fibroblast (NCTC clone 929 [L cell, L-929, derivative of Strain L] ATCC® CCL -1™).

2.2 Justification for selection of the cell culture
American Type Culture Collection CCL-1, NCTC clone 929 Areolar Fibroblast Mouse is used to evaluate the cytotoxic effect as recommended by ISO 10993 Part 5.

3.0 Material

Table 1 Information of material used

Materials	Brand name	Reference
Growth Medium: Eagle's Minimum Essential Medium (EMEM)	Gibco	61100-061
Foetal Bovine Serum	Gibco	10270-098
Penicillin Streptomycin (Antibiotic)	Sigma	P4333

4.0 Control item

4.1 Negative control: Polypropylene, Thermo Scientific 339650

4.2 Positive control: Zinc sulphate, Sigma Z0251

4.3 Medium control: Eagle's Minimum Essential Medium (EMEM), Gibco 61100-061

Tiller INTERNATIONAL CAPITAL

CE
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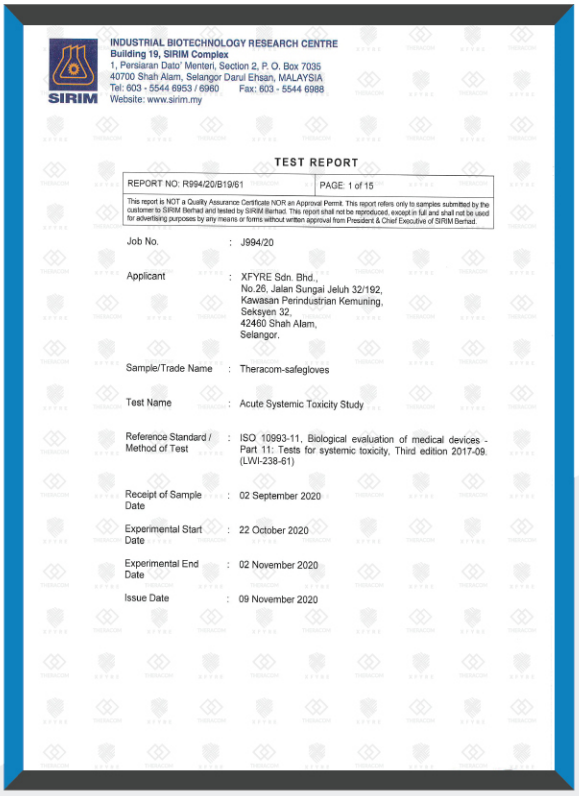
CE MARK 455-3 (ACUTE SYSTEMIC)

(MADE IN COMPLIANCE WITH 93/42/EEC)

CERTIFICATIONS



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TEST REPORT

REPORT NO: R994/20/B19/61 | PAGE: 1 of 15

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Job No.	:	J994/20
Applicant	:	XFYRE Sdn. Bhd., No.26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam, Selangor.
Sample/Trade Name	:	Theracom-safegloves
Test Name	:	Acute Systemic Toxicity Study
Reference Standard / Method of Test	:	ISO 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity, Third edition 2017-09. (LWI-238-61)
Receipt of Sample Date	:	02 September 2020
Experimental Start Date	:	22 October 2020
Experimental End Date	:	02 November 2020
Issue Date	:	09 November 2020

TEST REPORT

REPORT NO: R994/20/B19/61 | PAGE: 2 of 15

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APPROVED SIGNATORIES

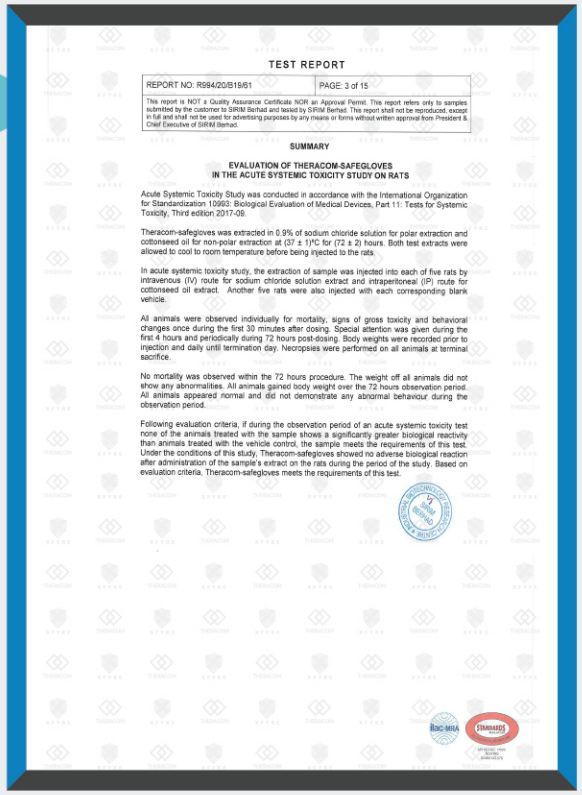
We, the undersigned, declare that the methods, results and data contained in this report faithfully reflect the procedures used and raw data collected throughout the study.

(SYAMIMI KHALID)
Reviewer
Industrial Biotechnology Research Centre

09 NOV 2020
Date

(NURHAYATI ARIFFIN)
Analyst
Industrial Biotechnology Research Centre

09 NOV 2020
Date



TEST REPORT

REPORT NO: R994/20/B19/61 | PAGE: 3 of 15

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SUMMARY

EVALUATION OF THERACOM-SAFEGLOVES IN THE ACUTE SYSTEMIC TOXICITY STUDY ON RATS

Acute Systemic Toxicity Study was conducted in accordance with the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity, Third edition 2017-09.

Theracom-safegloves was extracted in 0.9% of sodium chloride solution for polar extraction and cottonseed oil for non-polar extraction at (37 ± 1)°C for (72 ± 2) hours. Both test extracts were allowed to cool to room temperature before being injected to the rats.

In acute systemic toxicity study, the extraction of sample was injected into each of five rats by intravenous (IV) route for sodium chloride solution extract and intraperitoneal (IP) route for cottonseed oil extract. Another five rats were also injected with each corresponding blank vehicle.

All animals were observed individually for mortality, signs of gross toxicity and behavioral changes once during the first 30 minutes after dosing. Special attention was given during the first 4 hours and periodically during 72 hours post-dosing. Body weights were recorded prior to injection and daily until termination day. Necropsies were performed on all animals at terminal sacrifice.

No mortality was observed within the 72 hours procedure. The weight off all animals did not show any abnormalities. All animals gained body weight over the 72 hours observation period. All animals appeared normal and did not demonstrate any abnormal behaviour during the observation period.

Following evaluation criteria, if during the observation period of an acute systemic toxicity test none of the animals treated with the sample shows a significantly greater biological reactivity than animals treated with the vehicle control, the sample meets the requirements of this test. Under the conditions of this study, Theracom-safegloves showed no adverse biological reaction after administration of the sample's extract on the rats during the period of the study. Based on evaluation criteria, Theracom-safegloves meets the requirements of this test.

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CE MARK 455-3 (ENDOTOXIN)

(MADE IN COMPLIANCE WITH 93/42/EEC)

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TEST REPORT

REPORT NO: R1036 -01/20/B19/91	PAGE: 1 of 2

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Applicant : Orissa
Company : XFYRE (M) SDN. BHD.
Address : No. 26, Jalan Sungai Jeluh 32/192,
Kawasan Perindustrian Kemuning, Seksyen 32,
42460 Shah Alam, Selangor Darul Ehsan,
MALAYSIA.
Manufacturer : Not stated
Address : Not stated
Sample : Disposable glove
Reference standard / Method of Test : European Pharmacopoeia 8.0 (EP 2.6.14. Bacterial Endotoxin) Turbidimetric Kinetic Method
Description of sample : Received one (1) sample with the following identification for testing:

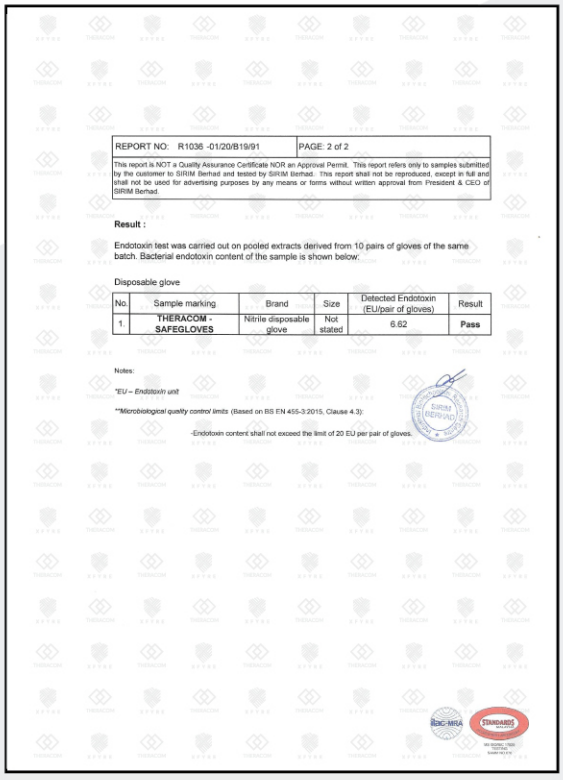
No.	Sample marking	Brand	Size	Quantity
1.	**THERACOM - SAFEGLOVES**	Nitrile disposable glove	Not stated	10 pairs

Date received : 11 September, 2020
Date test started : 15 September, 2020
Job No. : J1036 -01/20
Issue date : 17 September, 2020

Approved signatories.

(MOHD KHAIRUL AZWAN AHMAD)
MJMM 0481
Analyst,
Industrial Biotechnology Research Centre,
SIRIM Berhad

(MOHD MAHAYUDDIN HUSSIN)
MJMM 0482
Reviewer,
Industrial Biotechnology Research Centre,
SIRIM Berhad



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Result :

Endotoxin test was carried out on pooled extracts derived from 10 pairs of gloves of the same batch. Bacterial endotoxin content of the sample is shown below:

Disposable glove

No.	Sample marking	Brand	Size	Detected Endotoxin (EU/pair of gloves)	Result
1.	**THERACOM - SAFEGLOVES**	Nitrile disposable glove	Not stated	6.62	**Pass**

Notes:

**EU – Endotoxin unit*

***Microbiological quality control limits* (Based on BS EN 455-3:2015, Clause 4.3):

-Endotoxin content shall not exceed the limit of 20 EU per pair of gloves.

CONDITIONS RELATING TO THE USE OF SIRIM BERHAD TEST REPORT

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2. The Test Report shall not be amended, changed, varied or modified in any manner whatsoever by the Applicant or otherwise.
3. If the Test Report is to be furnished to any third party or to the public, each such Test Report shall be furnished in full, legible and in its entirety.
4. The Test Report shall not be reproduced and shall not in any event be used for any advertising purposes or whatsoever without written approval from the President & Chief Executive of SIRIM Berhad of No. 1, Persiaran Dato' Menteri, Building 5, Section 2, P. O. Box 7035, 40700 Shah Alam, Selangor Darul Ehsan.
5. Customer (Applicant/Manufacturer/Factory, etc.) is not permitted to use any SIRIM Berhad, other SIRIM Berhad's subsidiaries logo on packaging, sample's manual, technical specification, brochures/flyers or any other means.
6. If such approval is obtained from the President & Chief Executive, the Applicant may only include the phrase, "A sample of this product has been tested by SIRIM Berhad ... (Test Report No) ... (dated) ... (for what test) ... (to which standard)" or such similar words which stress that only the Sample was actually tested. This phrase shall only be used for the purpose of product advertisement or product promotion (eg; brochures). For avoidance of doubt, the statement shall not be used on the sample and packaging of the sample.
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8. Further or in the alternative, it is strictly forbidden to represent in any manner whatsoever that SIRIM Berhad and/or other SIRIM's subsidiaries has endorsed, approved or validated the Product of the Applicant in any manner whatsoever.
9. In the event the applicant is found in breach of this provision, SIRIM Berhad and/or other SIRIM's subsidiaries without prejudice to any other rights and remedies may take whatever action necessary including but not limited to:
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   b) Obtaining an injunction from Court (cost on a solicitor-client basis to be borne by the Applicant);
   c) Refusing to accept any further Product for Testing Services from the Applicant or whatsoever related to the Applicant, whether subsidiary or otherwise;
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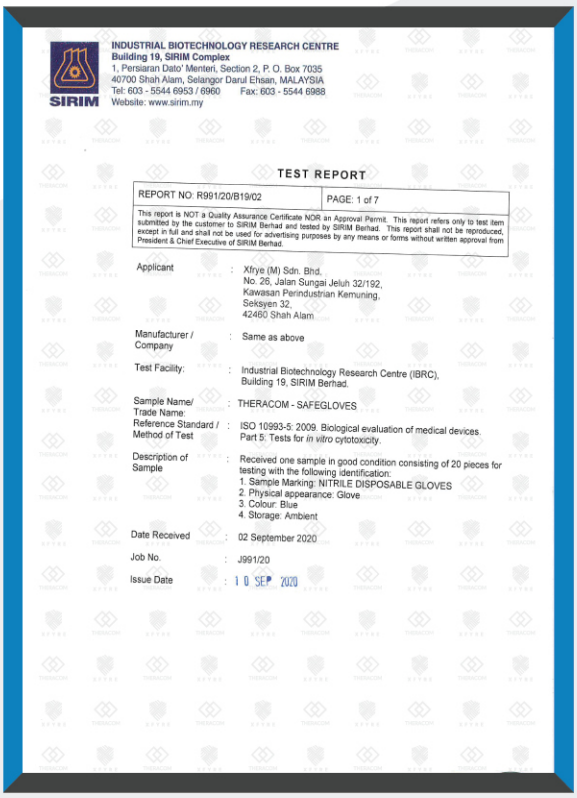
   e) Informing or lodging a report pertaining the Applicant's Test Report with the relevant authorities.
10. Certified true copies of the Test Report may be issued upon request by the applicant upon payment of the relevant fee.
11. Corrections to test report shall only be allowed within 6 months from issuance date of the Test Report of the relevant fee and shall be limited to maximum 3 times, after either case whichever occurs earlier, a new Test Report shall be issued and replace the previous one (having error(s) or lack of information) with relevant fee. Issuance of Supplementary Report to the original Test Report shall be for the followings:
    a) Misprints and typo errors;
    b) Missing technical information;
    c) Test data not reported;
    d) Mistake in reporting of test data.
12. Any amendment requested from customers on the test report issued shall be in writing.
13. SIRIM reserves the right in its sole discretion to terminate or modify this permission.

(Revision 1.3.2020)



INDUSTRIAL BIOTECHNOLOGY RESEARCH CENTRE
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40700 Shah Alam, Selangor Darul Ehsan, MALAYSIA
Tel: 603 - 5544 6953 / 6960 Fax: 603 - 5544 6988
Website: www.sirim.my

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TEST REPORT

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Applicant	:	Xfrye (M) Sdn. Bhd. No. 26, Jalan Sungai Jeluh 32/192, Kawasan Perindustrian Kemuning, Seksyen 32, 42460 Shah Alam
Manufacturer / Company	:	Same as above
Test Facility:	:	Industrial Biotechnology Research Centre (IBRC), Building 19, SIRIM Berhad.
Sample Name/ Trade Name	:	THERACOM - SAFEGLOVES
Reference Standard / Method of Test	:	ISO 10993-5: 2009. Biological evaluation of medical devices. Part 5: Tests for *in vitro* cytotoxicity.
Description of Sample	:	Received one sample in good condition consisting of 20 pieces for testing with the following identification: 1. Sample Marking: NITRILE DISPOSABLE GLOVES 2. Physical appearance: Glove 3. Colour: Blue 4. Storage: Ambient
Date Received	:	02 September 2020
Job No.	:	J991/20
Issue Date	:	10 SEP 2020

CE
EN455

CE MARK 455-3 (SKIN IRRITATION)

(MADE IN COMPLIANCE WITH 93/42/EEC)

CERTIFICATIONS

TEST REPORT

REPORT NO: R992/20/B19/57	PAGE: 2 of 14

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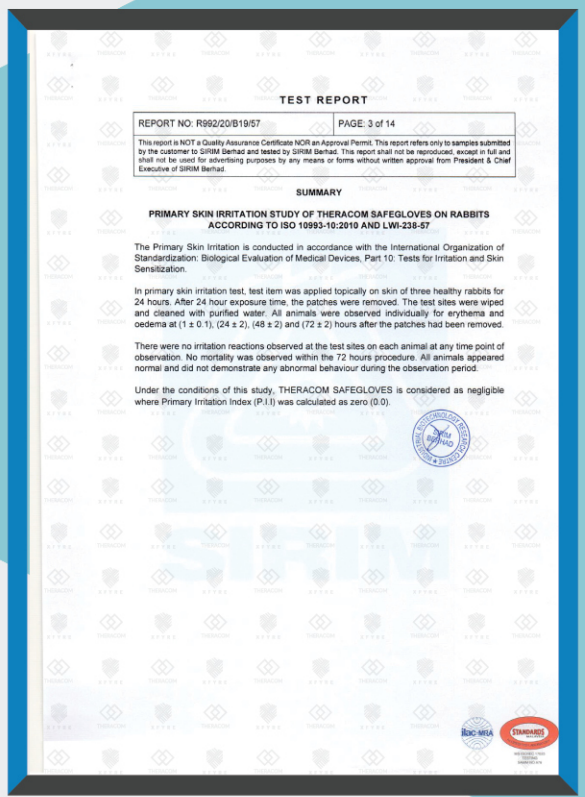
APPROVED SIGNATORIES

We, the undersigned, declare that the methods, results and data contained in this report faithfully reflect the procedures used and raw data collected throughout the study.

(JUANI MAZMIN HUSIN) Reviewer Industrial Biotechnology Research Centre	22 SEP 2020 Date
(SYAMIMI MD KHALID) Analyst Industrial Biotechnology Research Centre	22 SEP 2020 Date



TEST REPORT

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SUMMARY

PRIMARY SKIN IRRITATION STUDY OF THERACOM SAFEGLOVES ON RABBITS ACCORDING TO ISO 10993-10:2010 AND LWI-238-57

The Primary Skin Irritation is conducted in accordance with the International Organization of Standardization: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization.

In primary skin irritation test, test item was applied topically on skin of three healthy rabbits for 24 hours. After 24 hour exposure time, the patches were removed. The test sites were wiped and cleaned with purified water. All animals were observed individually for erythema and oedema at (1 ± 0.1), (24 ± 2), (48 ± 2) and (72 ± 2) hours after the patches had been removed.

There were no irritation reactions observed at the test sites on each animal at any time point of observation. No mortality was observed within the 72 hours procedure. All animals appeared normal and did not demonstrate any abnormal behaviour during the observation period.

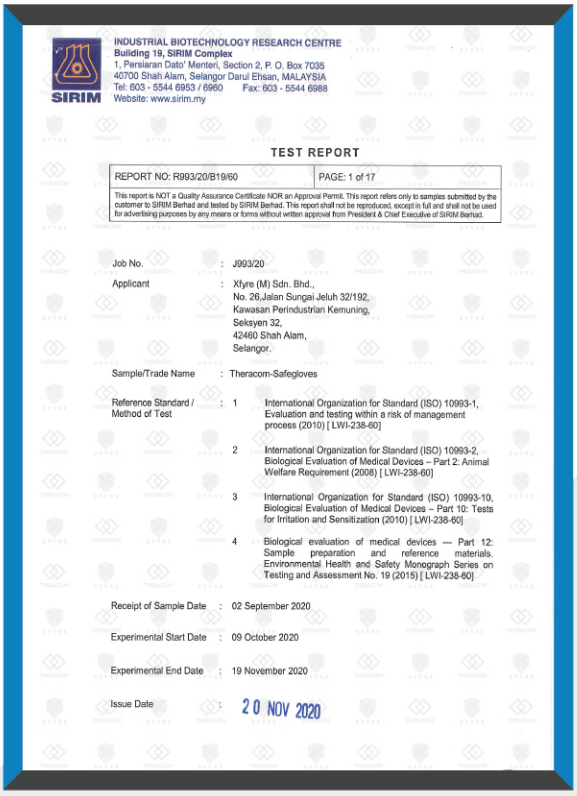
Under the conditions of this study, THERACOM SAFEGLOVES is considered as negligible where Primary Irritation Index (P.I.I) was calculated as zero (0.0).

CE
EN455

CE MARK 455-3 (SKIN SENSITIZATION)

(MADE IN COMPLIANCE WITH 93/42/EEC)

CERTIFICATIONS



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TEST REPORT

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Job No. : J993/20

Applicant : Xfyre (M) Sdn. Bhd.,
No. 26,Jalan Sungai Jeluh 32/192,
Kawasan Perindustrian Kemuning,
Seksyen 32,
42460 Shah Alam,
Selangor.

Sample/Trade Name : Theracom-Safegloves

Reference Standard / Method of Test :
1 International Organization for Standard (ISO) 10993-1, Evaluation and testing within a risk of management process (2010) [LWI-238-60]
2 International Organization for Standard (ISO) 10993-2, Biological Evaluation of Medical Devices – Part 2: Animal Welfare Requirement (2008) [LWI-238-60]
3 International Organization for Standard (ISO) 10993-10, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Sensitization (2010) [LWI-238-60]
4 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials. Environmental Health and Safety Monograph Series on Testing and Assessment No. 19 (2015) [LWI-238-60]

Receipt of Sample Date : 02 September 2020

Experimental Start Date : 09 October 2020

Experimental End Date : 19 November 2020

Issue Date : 20 NOV 2020

STUDY REPORT

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APPROVED SIGNATORIES

We, the undersigned, declare that the methods, results and data contained in this report faithfully reflect the procedures used and raw data collected throughout the study.

(JUANI MAZMIN HUSIN)
Reviewer
Industrial Biotechnology Research Centre
Date: 20 NOV 2020

(NOOR RABIHAH AID)
Analyst
Industrial Biotechnology Research Centre
Date: 20 NOV 2020

STUDY REPORT

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SUMMARY

SKIN SENSITISATION STUDY (CLOSED-PATCH TEST) OF THERACOM-SAFEGLOVES

A Closed-patch Test (Buehler Test) was conducted to determine the potential of the test item to produce skin sensitisation in guinea pigs. The test was conducted in in accordance with the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitisation.

In Closed-Patch Test (Buehler Test), ten guinea pigs were patched topically with the test item and five guinea pigs served as negative control group were patched in parallel in an identical way but without the test item. Test item was administered by topical application to the test sites of each animals. The patches were held in place by wrapping the trunk of the animals with a surgical tape and securing with self-adherent wrap.

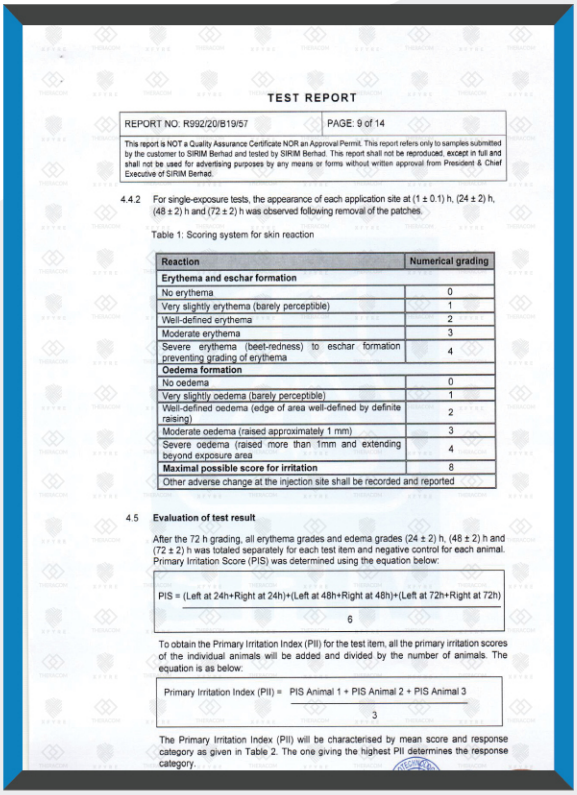
The patches were removed after (6 ± 0.5) hours of exposure. This procedure was repeated three times per week for three weeks, for a total of nine applications.

Following a (14 ± 1) day rest period after the final induction patch, the animals were topically patched with the appropriate test item on the test animals and the control on the control animals. The patches were removed after (6 ± 0.5) hours of exposure. The dermal patch sites were observed for erythema and edema (24 ± 2) hours and (48 ± 2) hours after patch removal.

Each animal was assessed for a sensitisation response based upon the dermal scores. The test substance is not considered to be a skin sensitiser since none of the test animals exhibited skin reaction scores at the challenge exposure following an induction phase. No reactions were observed in the negative control group.

Under the conditions of this study, **Theracom-Safegloves** did not induce sensitisation in the guinea pigs.

Tiller INTERNATIONAL CAPITAL



TEST REPORT

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4.4.2 For single-exposure tests, the appearance of each application site at (1 ± 0.1) h, (24 ± 2) h, (48 ± 2) h and (72 ± 2) h was observed following removal of the patches.

Table 1: Scoring system for skin reaction

Reaction	Numerical grading
Erythema and eschar formation	
No erythema	0
Very slightly erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet-redness) to eschar formation preventing grading of erythema	4
Oedema formation	
No oedema	0
Very slightly oedema (barely perceptible)	1
Well-defined oedema (edge of area well-defined by definite raising)	2
Moderate oedema (raised approximately 1 mm)	3
Severe oedema (raised more than 1mm and extending beyond exposure area	4
Maximal possible score for irritation	8
Other adverse change at the injection site shall be recorded and reported	

4.5 **Evaluation of test result**

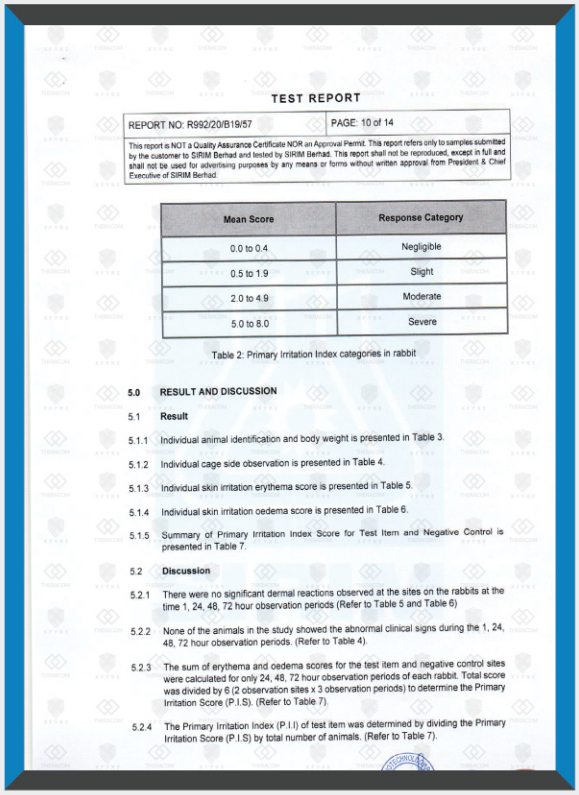
After the 72 h grading, all erythema grades and edema grades (24 ± 2) h, (48 ± 2) h and (72 ± 2) h was totaled separately for each test item and negative control for each animal. Primary Irritation Score (PIS) was determined using the equation below:

$$PIS = \frac{(Left\ at\ 24h + Right\ at\ 24h) + (Left\ at\ 48h + Right\ at\ 48h) + (Left\ at\ 72h + Right\ at\ 72h)}{6}$$

To obtain the Primary Irritation Index (PII) for the test item, all the primary irritation scores of the individual animals will be added and divided by the number of animals. The equation is as below:

$$Primary\ Irritation\ Index\ (PII) = \frac{PIS\ Animal\ 1 + PIS\ Animal\ 2 + PIS\ Animal\ 3}{3}$$

The Primary Irritation Index (PII) will be characterised by mean score and response category as given in Table 2. The one giving the highest PII determines the response category.



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Mean Score	Response Category
0.0 to 0.4	Negligible
0.5 to 1.9	Slight
2.0 to 4.9	Moderate
5.0 to 8.0	Severe

Table 2: Primary Irritation Index categories in rabbit

5.0 RESULT AND DISCUSSION

5.1 **Result**

5.1.1 Individual animal identification and body weight is presented in Table 3.

5.1.2 Individual cage side observation is presented in Table 4.

5.1.3 Individual skin irritation erythema score is presented in Table 5.

5.1.4 Individual skin irritation oedema score is presented in Table 6.

5.1.5 Summary of Primary Irritation Index Score for Test Item and Negative Control is presented in Table 7.

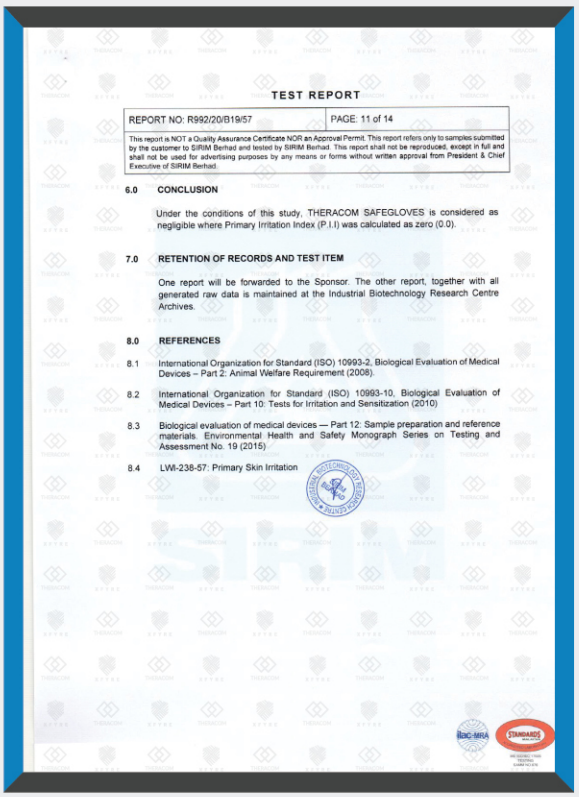
5.2 **Discussion**

5.2.1 There were no significant dermal reactions observed at the sites on the rabbits at the time 1, 24, 48, 72 hour observation periods (Refer to Table 5 and Table 6)

5.2.2 None of the animals in the study showed the abnormal clinical signs during the 1, 24, 48, 72 hour observation periods. (Refer to Table 4).

5.2.3 The sum of erythema and oedema scores for the test item and negative control sites were calculated for only 24, 48, 72 hour observation periods of each rabbit. Total score was divided by 6 (2 observation sites x 3 observation periods) to determine the Primary Irritation Score (P.I.S). (Refer to Table 7).

5.2.4 The Primary Irritation Index (P.I.I) of test item was determined by dividing the Primary Irritation Score (P.I.S) by total number of animals. (Refer to Table 7).



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6.0 CONCLUSION

Under the conditions of this study, THERACOM SAFEGLOVES is considered as negligible where Primary Irritation Index (P.I.I) was calculated as zero (0.0).

7.0 RETENTION OF RECORDS AND TEST ITEM

One report will be forwarded to the Sponsor. The other report, together with all generated raw data is maintained at the Industrial Biotechnology Research Centre Archives.

8.0 REFERENCES

8.1 International Organization for Standard (ISO) 10993-2, Biological Evaluation of Medical Devices – Part 2: Animal Welfare Requirement (2008).

8.2 International Organization for Standard (ISO) 10993-10, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Sensitization (2010)

8.3 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials. Environmental Health and Safety Monograph Series on Testing and Assessment No. 19 (2015)

8.4 LWI-238-57: Primary Skin Irritation

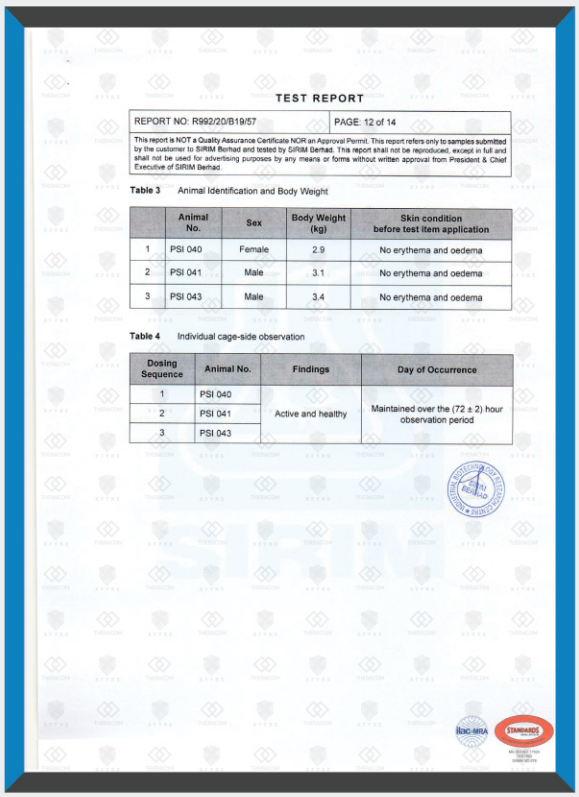

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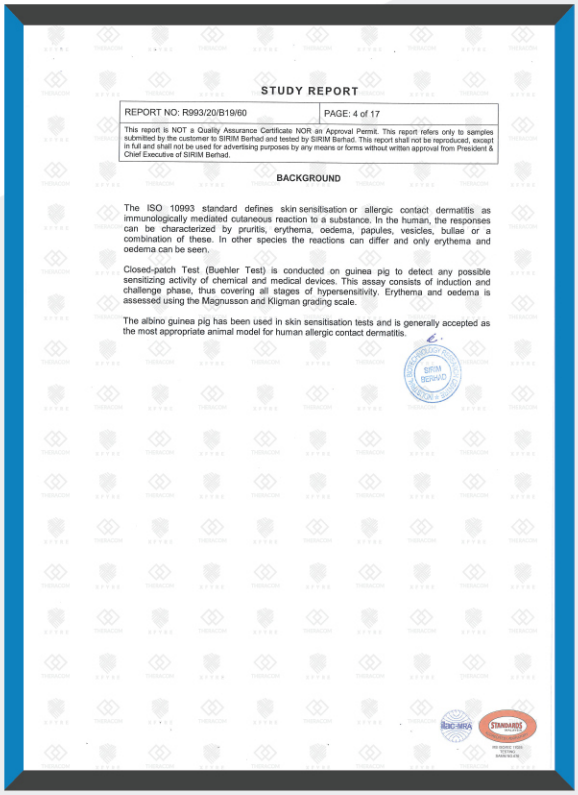
Table 3 Animal Identification and Body Weight

	Animal No.	Sex	Body Weight (kg)	Skin condition before test item application
1	PSI 040	Female	2.9	No erythema and oedema
2	PSI 041	Male	3.1	No erythema and oedema
3	PSI 043	Male	3.4	No erythema and oedema

Table 4 Individual cage-side observation

Dosing Sequence	Animal No.	Findings	Day of Occurrence
1	PSI 040	Active and healthy	Maintained over the (72 ± 2) hour observation period
2	PSI 041		
3	PSI 043		



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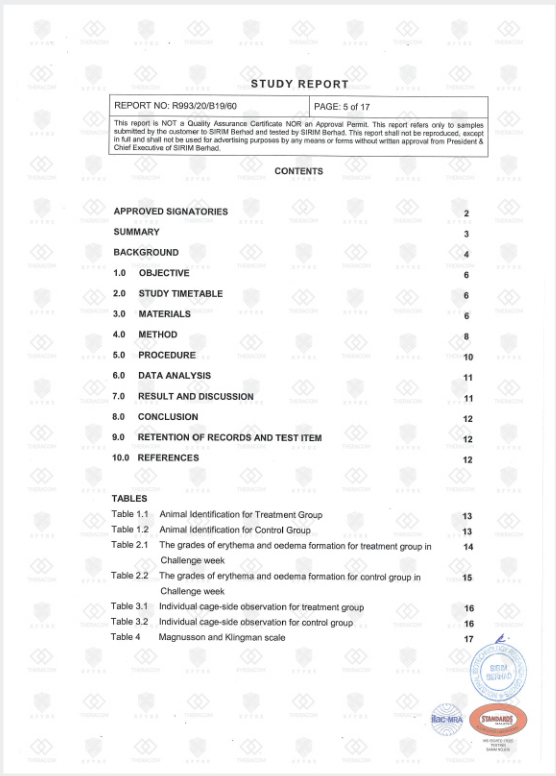
BACKGROUND

The ISO 10993 standard defines skin sensitisation or allergic contact dermatitis as immunologically mediated cutaneous reaction to a substance. In the human, the responses can be characterized by pruritis, erythema, oedema, papules, vesicles, bullae or a combination of these. In other species the reactions can differ and only erythema and oedema can be seen.

Closed-patch Test (Buehler Test) is conducted on guinea pig to detect any possible sensitizing activity of chemical and medical devices. This assay consists of induction and challenge phase, thus covering all stages of hypersensitivity. Erythema and oedema is assessed using the Magnusson and Kligman grading scale.

The albino guinea pig has been used in skin sensitisation tests and is generally accepted as the most appropriate animal model for human allergic contact dermatitis.



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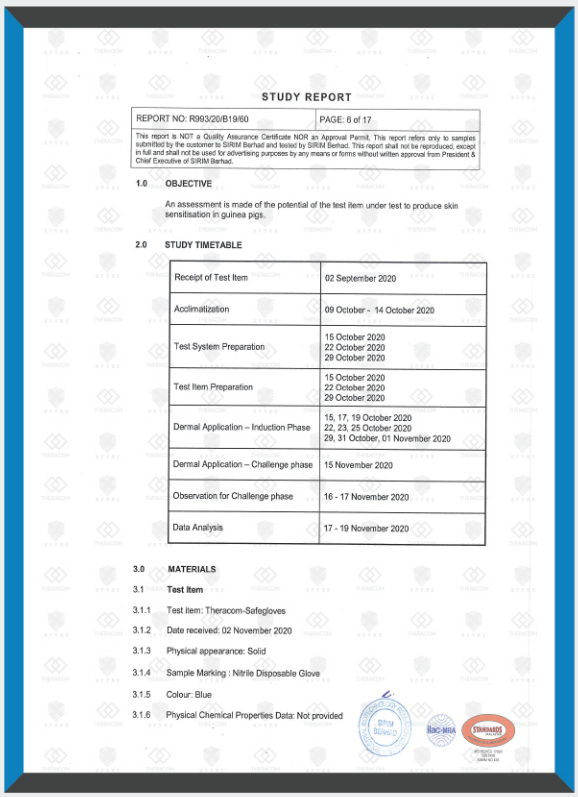

STUDY REPORT

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1.0 OBJECTIVE

An assessment is made of the potential of the test item under test to produce skin sensitisation in guinea pigs.

2.0 STUDY TIMETABLE

Receipt of Test Item	02 September 2020
Acclimatization	09 October – 14 October 2020
Test System Preparation	15 October 2020 22 October 2020 29 October 2020
Test Item Preparation	15 October 2020 22 October 2020 29 October 2020
Dermal Application – Induction Phase	15, 17, 19 October 2020 22, 23, 25 October 2020 29, 31 October, 01 November 2020
Dermal Application – Challenge phase	15 November 2020
Observation for Challenge phase	16 - 17 November 2020
Data Analysis	17 - 19 November 2020

3.0 MATERIALS

3.1 Test Item

3.1.1 Test Item: Theracom-Safegloves

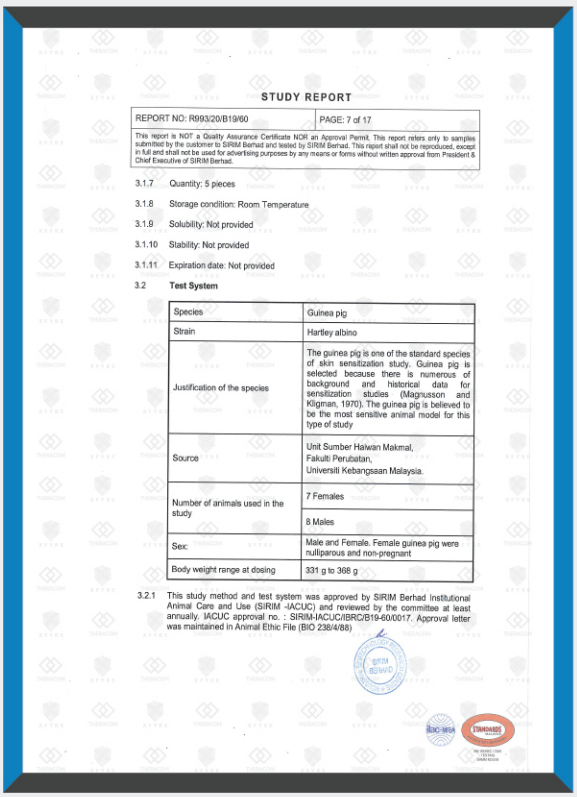
3.1.2 Date received: 02 November 2020

3.1.3 Physical appearance: Solid

3.1.4 Sample Marking : Nitrile Disposable Glove

3.1.5 Colour: Blue

3.1.6 Physical Chemical Properties Data: Not provided



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3.1.7 Quantity: 5 pieces

3.1.8 Storage condition: Room Temperature

3.1.9 Solubility: Not provided

3.1.10 Stability: Not provided

3.1.11 Expiration date: Not provided

3.2 Test System

Species	Guinea pig
Strain	Hartley albino
Justification of the species	The guinea pig is one of the standard species of skin sensitization study. Guinea pig is selected because there is numerous of background and historical data for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study
Source	Unit Sumber Haiwan Makmal, Fakulti Perubatan, Universiti Kebangsaan Malaysia.
Number of animals used in the study	7 Females 8 Males
Sex:	Male and Female. Female guinea pig were nulliparous and non-pregnant
Body weight range at dosing	331 g to 368 g

3.2.1 This study method and test system was approved by SIRIM Berhad Institutional Animal Care and Use (SIRIM -IACUC) and reviewed by the committee at least annually. IACUC approval no. : SIRIM-IACUC/IBRC/B19-60/0017. Approval letter was maintained in Animal Ethic File (BIO 238/4/88)

5.0 Test method

5.1 Test summary

The degree of cytotoxicity in a mammalian cell culture in response to the test item extracted and diluted in growth medium, Eagle's Minimum Essential Medium (EMEM) was determined. Extraction of **THERACOM - SAFEGLOVES** with extraction ratio of 0.2 g/mL was carried out at (37±1) °C for 24 hours using cell growth medium as extractant. Positive and negative controls were included in the study to verify the proper functioning of the test system. The test item was tested in triplicates at six concentrations: 100.0% (6.0 cm^2/mL), 50.0%, 25.0%, 12.5%, 6.25% and 3.125%. Treatment was carried out at (37±1) °C in a carbon dioxide incubator and assessment carried out after 24-hour incubation.

5.2 Significance and rationale

This method is useful for assessing the cytotoxic potential of new materials and formulations and as part of a quality control program for established medical devices and components. Assessment of cytotoxicity provides useful information in predicting the potential clinical applications in human. Cell culture methods have shown good correlation with animal assays and are frequently more sensitive to cytotoxic agents.

5.3 Test procedure

The procedure was divided into three stages as follows.

5.3.1 Cell culture maintenance

Cells were grown in tissue culture grade flasks and routinely examined to ensure they remain healthy. Cells were seeded into 24-well plate and incubated until attaining confluence or near confluence monolayer growth before the treatment procedure.

5.3.2 Preparation of test item

The test item was extracted in the extraction vehicle to give a final extract concentration of approximately 6.0 cm^2/mL which is considered 100% as total extract. The positive and negative controls included were zinc sulphate and polypropylene, respectively. Growth medium was used as the extraction vehicle. The test item and controls were extracted/prepared in the growth medium and incubated simultaneously at (37±1) °C for 24 hours. After completion of extraction period, test item in the extraction vehicle were removed in sterile condition. Then the serial dilution from 100 % until 3.125% concentration was performed.

Table 2: Preparation of Test Item

Group	Extraction Ratio	Test Item amount	Volume of Extraction Vehicle	Extraction Condition
Test Item	6.0 cm^2/mL	6.0 cm^2	10.0 mL	(37±1) °C for 24 hours
Negative Control	0.2 g/mL	1.855 g	9.275 mL	(37±1) °C for 24 hours
Positive Control	0.0008 g/mL	0.0107 g	13.375 mL	(37±1) °C for 24 hours
Control Medium	-	-	20.0 mL	(37±1) °C for 24 hours

5.3.3 Effect on cell culture

The extract was tested at six concentrations, in growth media: 100.0% (6.0 cm^2/mL), 50.0%, 25.0%, 12.5%, 6.25% and 3.125%. Growth medium from the 24-well plate was replaced with test extracts, in triplicate wells at each concentration. The positive, negative and growth medium controls were included in the study. The plate was incubated for 24 hours at (37±1) °C in a humidified atmosphere of 5% carbon dioxide and 95% air.

5.4 Assessment of result

5.4.1 The condition of test item extraction before and after extraction period was observed.

5.4.2 The condition of cultures in each well, before and after treatment, was examined microscopically and graded. The qualitative morphological grading of cytotoxicity is presented in Table 3.

Table 3 Qualitative cytotoxicity grade

Grade	Reactivity	Conditions of cultures
0	None	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Mild	Not more than 50% of the cells are round, devoid of intracytoplasmatic granules, no extensive cell lysis; not more than 50% growth inhibition observable.
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observable.
4	Severe	Nearly complete or complete destruction of the cell layers.

6.0 Results

6.1 At the completion of the extraction period the physical of test item appeared unchanged by the extraction procedure. The extracts were not filter prior to being applied to the cell monolayer. The extracts were used immediately after the completion of the extraction period. Condition of extracts is presented in Table 4.

Table 4 Condition of extracts

Extraction	Conditions of extract	
	Before extraction	After extraction
Test item	Clear	Clear
Medium control	Clear	Clear
Negative control	Clear	Clear
Positive control	Clear	Clear

6.2 Microscopic examination of cultures before and after treatment with test extracts and controls, each in triplicate wells, are presented in Table 5.

Table 5 Conditions of cultures before and after treatment

Test extracts and controls	Conditions of cultures	
	Before treatment	After treatment
Test extract, 100.0 %	Subconfluent monolayer	Nearly complete or complete destruction of the cell layers in all wells
Test extract, 50.0 %	Subconfluent monolayer	Nearly complete or complete destruction of the cell layers in all wells
Test extract, 25.0 %	Subconfluent monolayer	Nearly complete or complete destruction of the cell layers in all wells
Test extract, 12.5 %	Subconfluent monolayer	Nearly complete or complete destruction of the cell layers in all wells
Test extract, 6.25 %	Subconfluent monolayer	More than 70% growth inhibition observable in two wells and not more than 50% growth inhibition observable in one well
Test extract, 3.125 %	Subconfluent monolayer	More than 50% growth inhibition observable in two wells and not more than 20% growth inhibition observable in one well
Medium control	Subconfluent monolayer	No cell lysis and reduction of cell growth in all wells
Negative control	Subconfluent monolayer	No cell lysis and reduction of cell growth in all wells
Positive control	Subconfluent monolayer	Nearly complete or complete destruction of the cell layers in all wells with 200 µg/mL zinc sulphate

7.0 Analysis and interpretation

Conditions of cultures after treatment (from Table 4), each in triplicate wells, was qualitatively graded according to Table 3 and presented in Table 6.

Table 6 Summary of cytotoxic gradings on cultures

Test extracts and controls	Grade	Reactivity
Test extract, 100.0 %	4-4-4	Severe
Test extract, 50.0 %	4-4-4	Severe
Test extract, 25.0 %	4-4-4	Severe
Test extract, 12.5 %	4-4-4	Severe
Test extract, 6.25 %	3-2-3	Moderate
Test extract, 3.125 %	2-2-1	Mild
Medium control	0-0-0	None
Negative control	0-0-0	None
Positive control	4-4-4	Severe

8.0 Conclusion

The test item **THERACOM - SAFEGLOVES** exhibited severe cytotoxicity reactivity at 100.0% to 12.5% extract concentrations, moderate cytotoxicity reactivity at 6.25% extract concentrations and mild cytotoxicity reactivity at 3.125% extract concentrations under the conditions of this test.

9.0 Reference

9.1 Biological evaluation of medical devices — Part 5: Tests for *in vitro* cytotoxicity

9.2 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials

9.3 Laboratory Working Instruction-238-02: Cytotoxicity Test for Medical Devices

Certifications

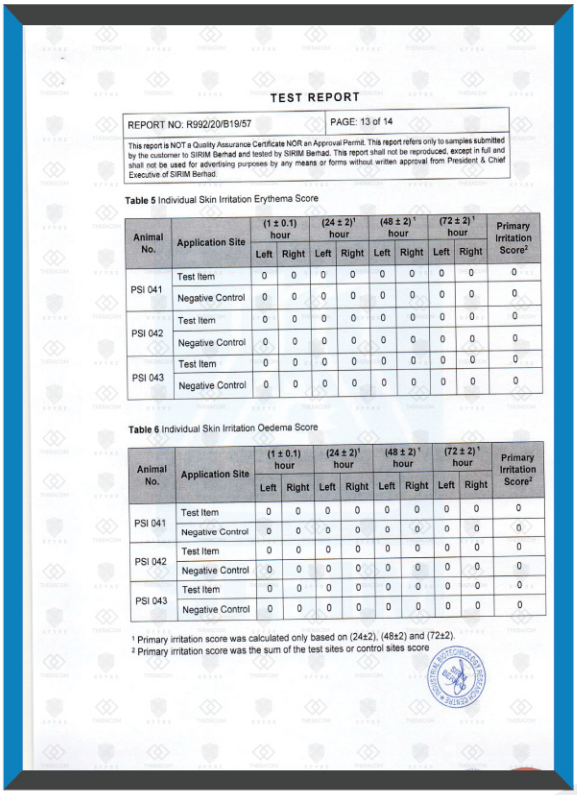

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Table 5 Individual Skin Irritation Erythema Score

Animal No.	Application Site	(1 ± 0.1) hour		(24 ± 2)[1] hour		(48 ± 2)[1] hour		(72 ± 2)[1] hour		Primary Irritation Score[2]
		Left	Right	Left	Right	Left	Right	Left	Right	
PSI 041	Test Item	0	0	0	0	0	0	0	0	0
	Negative Control	0	0	0	0	0	0	0	0	0
PSI 042	Test Item	0	0	0	0	0	0	0	0	0
	Negative Control	0	0	0	0	0	0	0	0	0
PSI 043	Test Item	0	0	0	0	0	0	0	0	0
	Negative Control	0	0	0	0	0	0	0	0	0

Table 6 Individual Skin Irritation Oedema Score

Animal No.	Application Site	(1 ± 0.1) hour		(24 ± 2)[1] hour		(48 ± 2)[1] hour		(72 ± 2)[1] hour		Primary Irritation Score[2]
		Left	Right	Left	Right	Left	Right	Left	Right	
PSI 041	Test Item	0	0	0	0	0	0	0	0	0
	Negative Control	0	0	0	0	0	0	0	0	0
PSI 042	Test Item	0	0	0	0	0	0	0	0	0
	Negative Control	0	0	0	0	0	0	0	0	0
PSI 043	Test Item	0	0	0	0	0	0	0	0	0
	Negative Control	0	0	0	0	0	0	0	0	0

[1] Primary irritation score was calculated only based on (24±2), (48±2) and (72±2).
[2] Primary irritation score was the sum of the test sites or control sites score

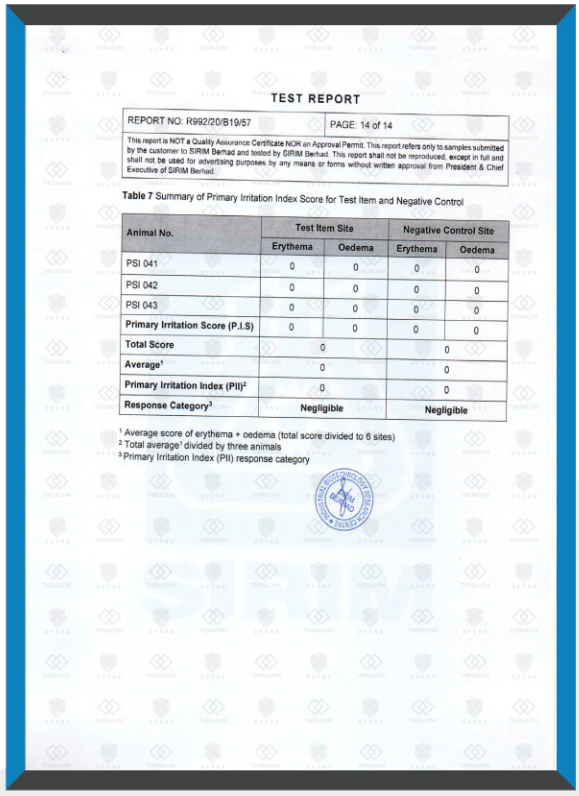

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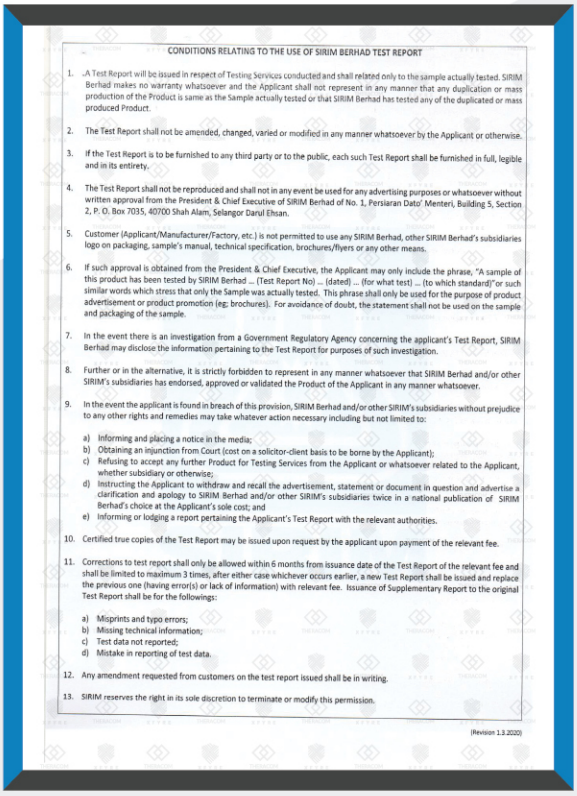
Table 7 Summary of Primary Irritation Index Score for Test Item and Negative Control

Animal No.	Test Item Site		Negative Control Site	
	Erythema	Oedema	Erythema	Oedema
PSI 041	0	0	0	0
PSI 042	0	0	0	0
PSI 043	0	0	0	0
Primary Irritation Score (P.I.S)	0	0	0	0
Total Score	0		0	
Average[1]	0		0	
Primary Irritation Index (PII)[2]	0		0	
Response Category[3]	**Negligible**		**Negligible**	

[1] Average score of erythema + oedema (total score divided to 6 sites)
[2] Total average[1] divided by three animals
[3] Primary Irritation Index (PII) response category



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    b) Missing technical information;
    c) Test data not reported;
    d) Mistake in reporting of test data.
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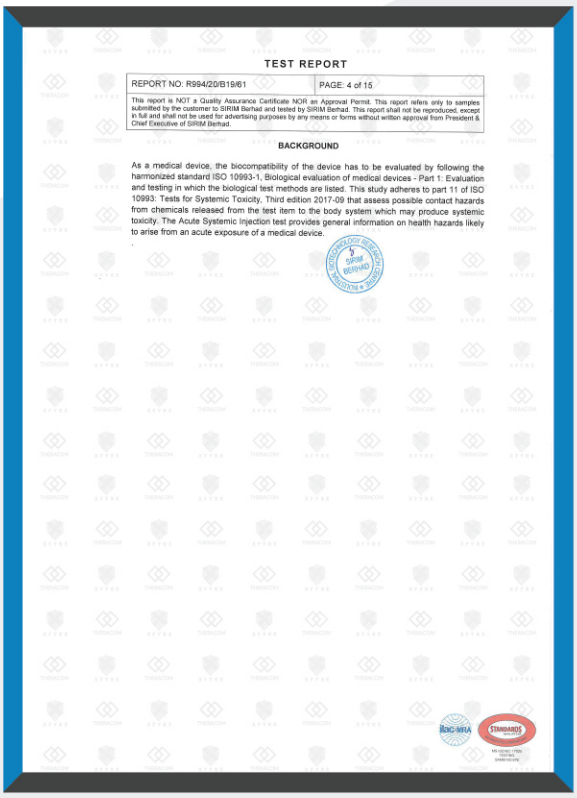

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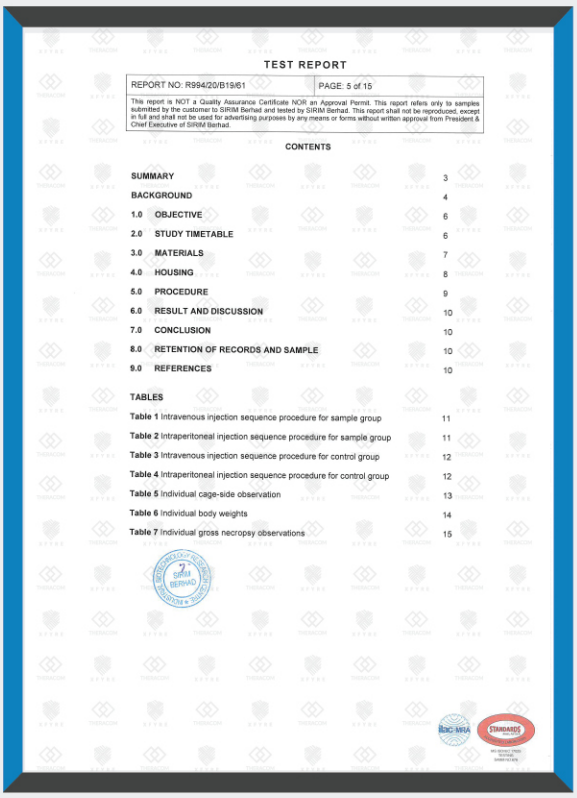
BACKGROUND

As a medical device, the biocompatibility of the device has to be evaluated by following the harmonized standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing in which the biological test methods are listed. This study adheres to part 11 of ISO 10993: Tests for Systemic Toxicity, Third edition 2017-09 that assess possible contact hazards from chemicals released from the test item to the body system which may produce systemic toxicity. The Acute Systemic Injection test provides general information on health hazards likely to arise from an acute exposure of a medical device.



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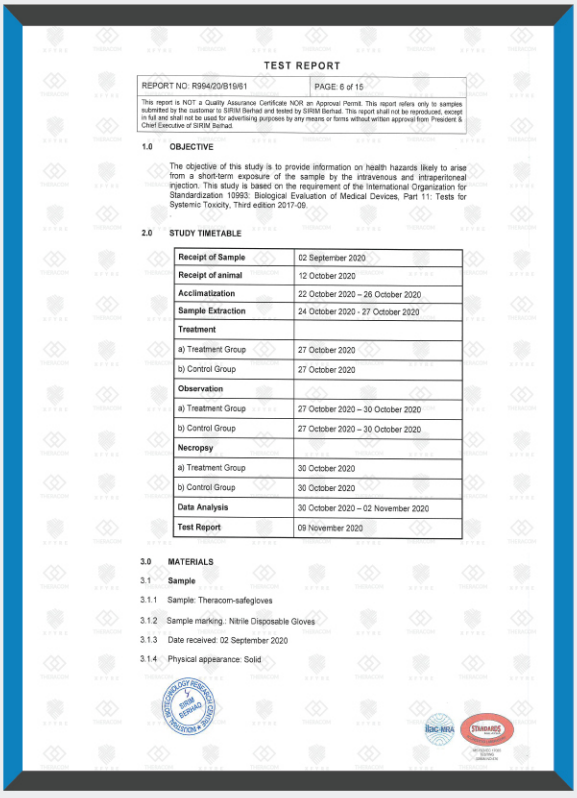

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1.0 OBJECTIVE

The objective of this study is to provide information on health hazards likely to arise from a short-term exposure of the sample by the intravenous and intraperitoneal injection. This study is based on the requirement of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity, Third edition 2017-09.

2.0 STUDY TIMETABLE

Receipt of Sample	02 September 2020
Receipt of animal	12 October 2020
Acclimatization	22 October 2020 – 26 October 2020
Sample Extraction	24 October 2020 - 27 October 2020
Treatment	
a) Treatment Group	27 October 2020
b) Control Group	27 October 2020
Observation	
a) Treatment Group	27 October 2020 – 30 October 2020
b) Control Group	27 October 2020 – 30 October 2020
Necropsy	
a) Treatment Group	30 October 2020
b) Control Group	30 October 2020
Data Analysis	30 October 2020 – 02 November 2020
Test Report	09 November 2020

3.0 MATERIALS

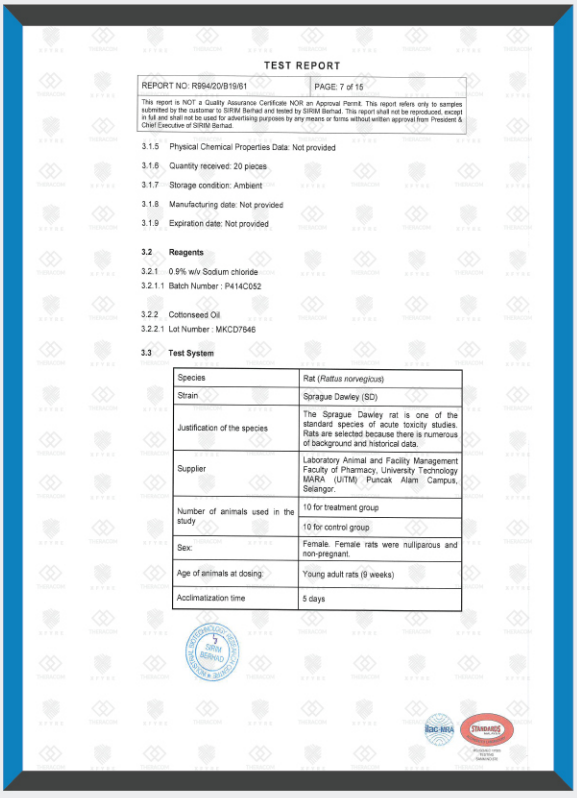
3.1 **Sample**

3.1.1 Sample: Theracom-safegloves

3.1.2 Sample marking.: Nitrile Disposable Gloves

3.1.3 Date received: 02 September 2020

3.1.4 Physical appearance: Solid



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3.1.5 Physical Chemical Properties Data: Not provided

3.1.6 Quantity received: 20 pieces

3.1.7 Storage condition: Ambient

3.1.8 Manufacturing date: Not provided

3.1.9 Expiration date: Not provided

3.2 **Reagents**

3.2.1 0.9% w/v Sodium chloride

3.2.1.1 Batch Number : P414C052

3.2.2 Cottonseed Oil

3.2.2.1 Lot Number : MKCD7846

3.3 **Test System**

Species	Rat (*Rattus norvegicus*)
Strain	Sprague Dawley (SD)
Justification of the species	The Sprague Dawley rat is one of the standard species of acute toxicity studies. Rats are selected because there is numerous of background and historical data.
Supplier	Laboratory Animal and Facility Management Faculty of Pharmacy, University Technology MARA (UiTM) Puncak Alam Campus, Selangor.
Number of animals used in the study	10 for treatment group
	10 for control group
Sex:	Female. Female rats were nulliparous and non-pregnant.
Age of animals at dosing:	Young adult rats (9 weeks)
Acclimatization time	5 days

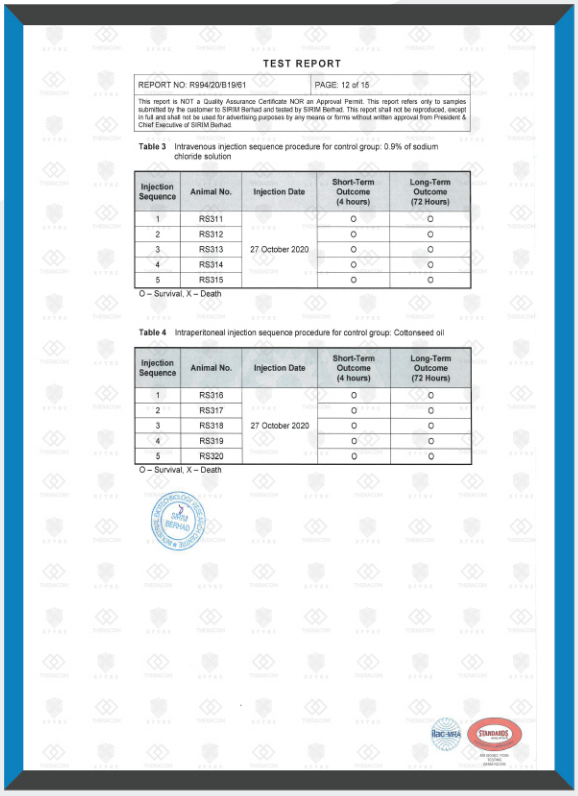

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Table 3 Intravenous injection sequence procedure for control group: 0.9% of sodium chloride solution

Injection Sequence	Animal No.	Injection Date	Short-Term Outcome (4 hours)	Long-Term Outcome (72 Hours)
1	RS311	27 October 2020	O	O
2	RS312		O	O
3	RS313		O	O
4	RS314		O	O
5	RS315		O	O

O – Survival, X – Death

Table 4 Intraperitoneal injection sequence procedure for control group: Cottonseed oil

Injection Sequence	Animal No.	Injection Date	Short-Term Outcome (4 hours)	Long-Term Outcome (72 Hours)
1	RS316	27 October 2020	O	O
2	RS317		O	O
3	RS318		O	O
4	RS319		O	O
5	RS320		O	O

O – Survival, X – Death

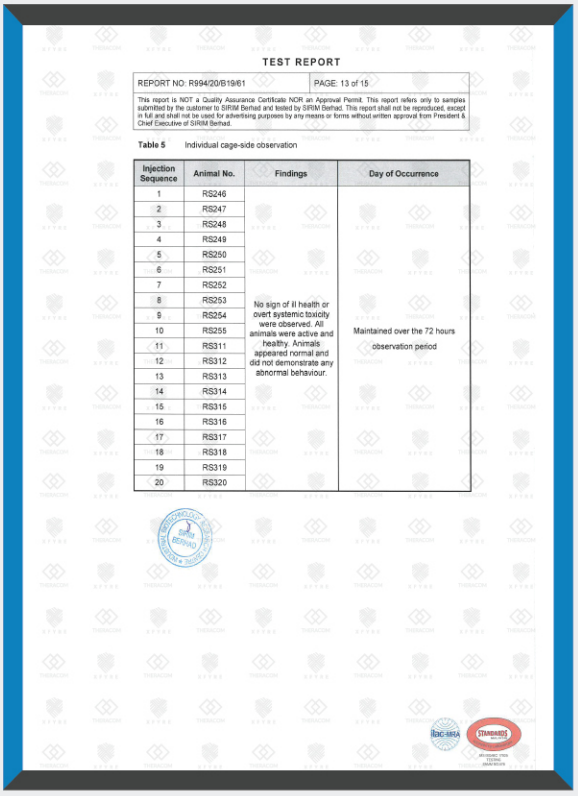

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Table 5 Individual cage-side observation

Injection Sequence	Animal No.	Findings	Day of Occurrence
1	RS246	No sign of ill health or overt systemic toxicity were observed. All animals were active and healthy. Animals appeared normal and did not demonstrate any abnormal behaviour.	Maintained over the 72 hours observation period
2	RS247		
3	RS248		
4	RS249		
5	RS250		
6	RS251		
7	RS252		
8	RS253		
9	RS254		
10	RS255		
11	RS311		
12	RS312		
13	RS313		
14	RS314		
15	RS315		
16	RS316		
17	RS317		
18	RS318		
19	RS319		
20	RS320		

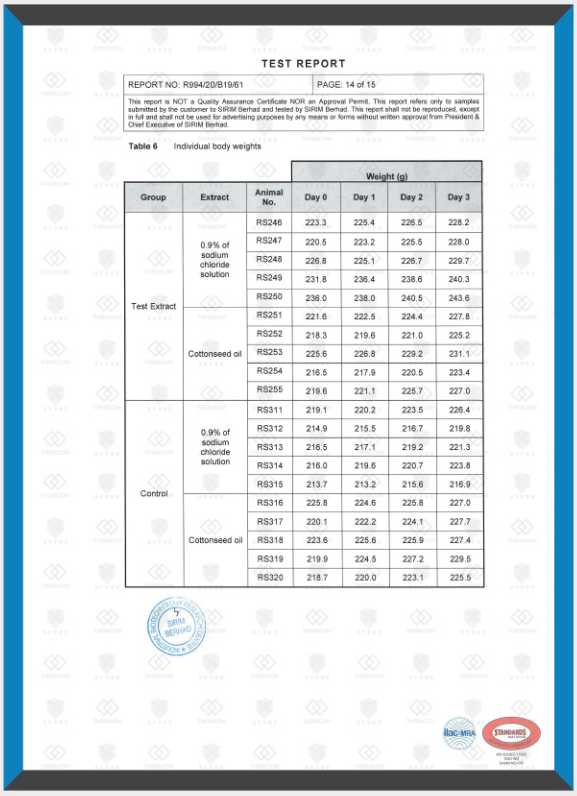

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Table 6 Individual body weights

Group	Extract	Animal No.	Weight (g) Day 0	Day 1	Day 2	Day 3
Test Extract	0.9% of sodium chloride solution	RS246	223.3	225.4	226.5	228.2
		RS247	220.5	223.2	225.5	228.0
		RS248	226.8	225.1	226.7	229.7
		RS249	231.8	236.4	238.6	240.3
		RS250	236.0	238.0	240.5	243.6
	Cottonseed oil	RS251	221.6	222.5	224.4	227.8
		RS252	218.3	219.6	221.0	225.2
		RS253	225.6	226.8	229.2	231.1
		RS254	216.5	217.9	220.5	223.4
		RS255	219.6	221.1	225.7	227.0
Control	0.9% of sodium chloride solution	RS311	219.1	220.2	223.5	226.4
		RS312	214.9	215.5	216.7	219.8
		RS313	216.5	217.1	219.2	221.3
		RS314	216.0	219.6	220.7	223.8
		RS315	213.7	213.2	215.6	216.9
	Cottonseed oil	RS316	225.8	224.6	225.8	227.0
		RS317	220.1	222.2	224.1	227.7
		RS318	223.6	225.6	225.9	227.4
		RS319	219.9	224.5	227.2	229.5
		RS320	218.7	220.0	223.1	225.5

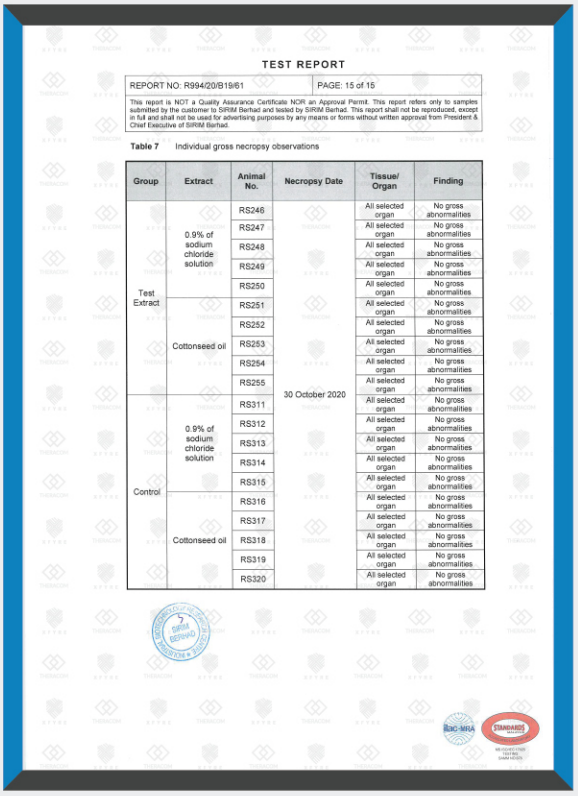

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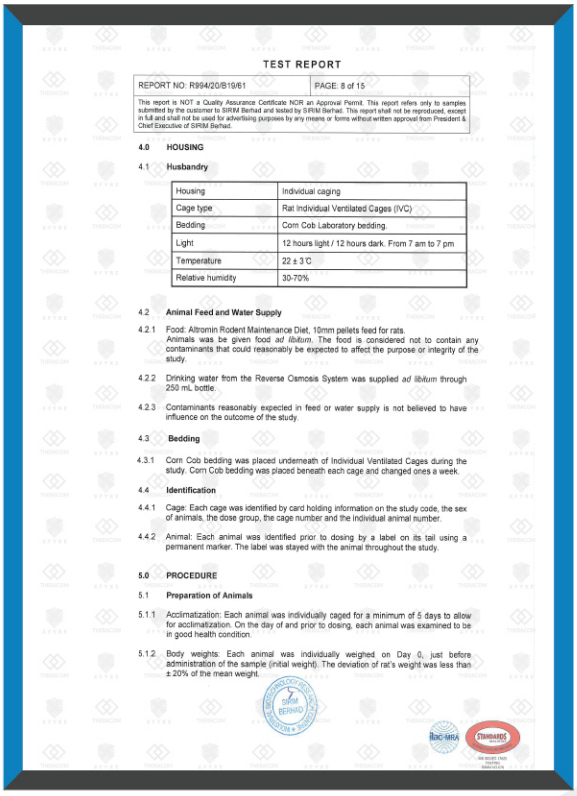
Table 7 Individual gross necropsy observations

Group	Extract	Animal No.	Necropsy Date	Tissue/ Organ	Finding
Test Extract	0.9% of sodium chloride solution	RS246	30 October 2020	All selected organ	No gross abnormalities
		RS247		All selected organ	No gross abnormalities
		RS248		All selected organ	No gross abnormalities
		RS249		All selected organ	No gross abnormalities
		RS250		All selected organ	No gross abnormalities
	Cottonseed oil	RS251		All selected organ	No gross abnormalities
		RS252		All selected organ	No gross abnormalities
		RS253		All selected organ	No gross abnormalities
		RS254		All selected organ	No gross abnormalities
		RS255		All selected organ	No gross abnormalities
Control	0.9% of sodium chloride solution	RS311		All selected organ	No gross abnormalities
		RS312		All selected organ	No gross abnormalities
		RS313		All selected organ	No gross abnormalities
		RS314		All selected organ	No gross abnormalities
		RS315		All selected organ	No gross abnormalities
	Cottonseed oil	RS316		All selected organ	No gross abnormalities
		RS317		All selected organ	No gross abnormalities
		RS318		All selected organ	No gross abnormalities
		RS319		All selected organ	No gross abnormalities
		RS320		All selected organ	No gross abnormalities

Certifications



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4.0 HOUSING

4.1 **Husbandry**

Housing	Individual caging
Cage type	Rat Individual Ventilated Cages (IVC)
Bedding	Corn Cob Laboratory bedding.
Light	12 hours light / 12 hours dark. From 7 am to 7 pm
Temperature	22 ± 3°C
Relative humidity	30-70%

4.2 **Animal Feed and Water Supply**

4.2.1 Food: Altromin Rodent Maintenance Diet, 10mm pellets feed for rats. Animals was be given food *ad libitum*. The food is considered not to contain any contaminants that could reasonably be expected to affect the purpose or integrity of the study.

4.2.2 Drinking water from the Reverse Osmosis System was supplied *ad libitum* through 250 mL bottle.

4.2.3 Contaminants reasonably expected in feed or water supply is not believed to have influence on the outcome of the study.

4.3 **Bedding**

4.3.1 Corn Cob bedding was placed underneath of Individual Ventilated Cages during the study. Corn Cob bedding was placed beneath each cage and changed ones a week.

4.4 **Identification**

4.4.1 Cage: Each cage was identified by card holding information on the study code, the sex of animals, the dose group, the cage number and the individual animal number.

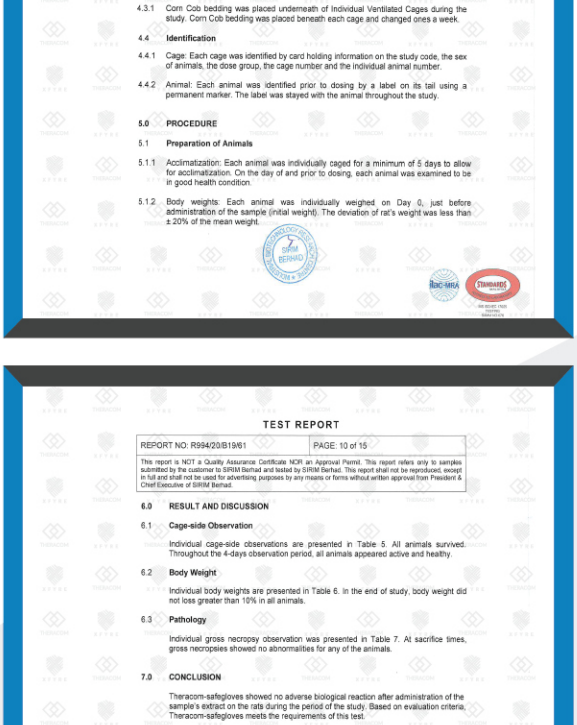
4.4.2 Animal: Each animal was identified prior to dosing by a label on its tail using a permanent marker. The label was stayed with the animal throughout the study.

5.0 PROCEDURE

5.1 **Preparation of Animals**

5.1.1 Acclimatization: Each animal was individually caged for a minimum of 5 days to allow for acclimatization. On the day of and prior to dosing, each animal was examined to be in good health condition.

5.1.2 Body weights: Each animal was individually weighed on Day 0, just before administration of the sample (initial weight). The deviation of rat's weight was less than ±20% of the mean weight.



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5.2 **Preparation of Sample**

Extraction of sample: The sample was extracted in extraction vehicle to give a final extract concentration of approximately 6 cm^2/mL extraction ratio. The extraction procedure was carried out at (37±1)°C for (72±2) hours. The test extracts were allowed to cool and administered to the animals within 24 hours.

5.2.2 The extraction vehicles:

5.2.2.1 Polar extract : 0.9% of sodium chloride solution

5.2.2.2 Non-polar extract : Cottonseed oil

5.2.3 The untreated 0.9% of sodium chloride solution and cottonseed oil were used as the extraction vehicle represent as control and incubated simultaneously at (37 ± 1)°C for (72 ± 2) hours.

5.3 **Route of exposure**

5.3.1 Routes of administration: The routes were selected based on recommendation from the guidelines of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity, Third edition 2017-09.

5.3.2 Intravenous Injection: Appropriate for devices with a direct or indirect fluid-path or blood contact environment conducive to chemical leaching. The extract of sample and control in 0.9% of sodium chloride was typically administered directly to the vascular system via lateral tail vein.

5.3.3 Intraperitoneal Injection: Appropriate for devices with a fluid-path or peritoneal cavity contact environment conducive to chemical leaching. The extract of samples and control in cottonseed oil was typically administered directly to the peritoneal cavity.

5.4 **Preparation of Dosing**

5.3.4 Dose level: Dose level was selected based on recommendation from the guidelines of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity, Third edition 2017-09.

5.4.2 Dose volume:

5.4.2.1 Polar extract: 40 mL/kg of rat body weight

5.4.2.2 Non-polar extract: 20 mL/kg of rat body weight

5.5 **Observation**

5.5.1 Cage-side observation: The animals was individually observed for mortality and signs of illness, injury or abnormal behaviour, once during the first 30 minutes after dosing, periodically during the first 24 hours (with special attention given during the first 4 hours), and daily thereafter for a total of 72 hours.

5.5.2 Body weight: Each animal was individually weighed on daily basis.

5.5.3 Pathology: All animals were subjected to a necropsy and a macroscopic examination. After examination of the external appearance, the cranial, thoracic and abdominal cavities were opened and the appearance of the organs were observed.

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6.0 RESULT AND DISCUSSION

6.1 **Cage-side Observation**

Individual cage-side observations are presented in Table 5. All animals survived. Throughout the 4-days observation period, all animals appeared active and healthy.

6.2 **Body Weight**

Individual body weights are presented in Table 6. In the end of study, body weight did not loss greater than 10% in all animals.

6.3 **Pathology**

Individual gross necropsy observation was presented in Table 7. At sacrifice times, gross necropsies showed no abnormalities for any of the animals.

7.0 CONCLUSION

Theracom-safegloves showed no adverse biological reaction after administration of the sample's extract on the rats during the period of the study. Based on evaluation criteria, Theracom-safegloves meets the requirements of this test.

8.0 RETENTION OF RECORDS AND SAMPLE

One report will be forwarded to the Sponsor. The other report, together with all generated raw data is maintained at the Industrial Biotechnology Research Centre Archives.

9.0 REFERENCES

9.1 ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing

9.2 ISO 10993-2:2006, Biological evaluation of medical devices - Part 2: Animal welfare Requirements

9.3 ISO 10993-11:2017, Biological evaluation of medical devices — Part 11: Tests for Systemic Toxicity

9.4 ISO 10993-12:2012, Biological evaluation of medical devices — Part 12: Sample preparation and reference materials

9.5 Principles and Methods of Toxicology, 5th Ed (2008). Edited by A Wallace Hayes, CRC Press.

9.6 (LWI-238-61) – Tests for Systemic Toxicity

TEST REPORT

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Table 1 Intravenous injection sequence procedure for sample group: Extraction in 0.9% of sodium chloride solution

Injection Sequence	Animal No.	Injection Date	Short-Term Outcome (4 hours)	Long-Term Outcome (72 hours)
1	RS246	27 October 2020	O	O
2	RS247		O	O
3	RS248		O	O
4	RS249		O	O
5	RS250		O	O

O – Survival, X – Death

Table 2 Intraperitoneal injection sequence procedure for sample group: Extraction in cottonseed oil

Injection Sequence	Animal No.	Injection Date	Short-Term Outcome (4 hours)	Long-Term Outcome (72 hours)
1	RS251	27 October 2020	O	O
2	RS252		O	O
3	RS253		O	O
4	RS254		O	O
5	RS255		O	O

O – Survival, X – Death