mCare

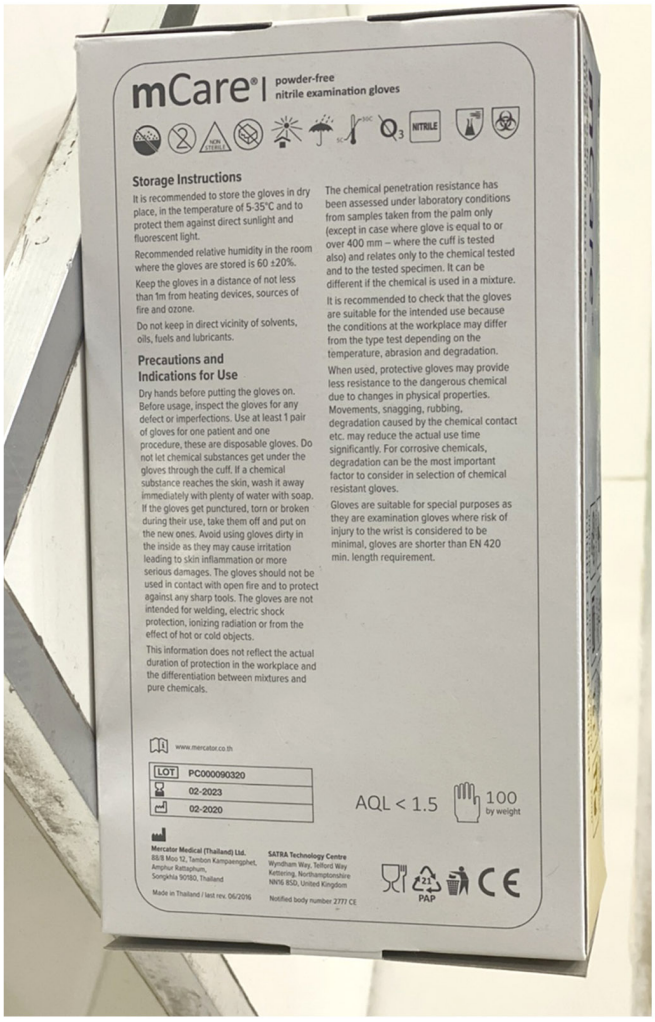
OEM PRODUCT by Mercator Medical (Thailand) co.,Ltd

At Mercator Medical Thailand, we are highly committed to the manufacturing of high quality examination gloves and to deliver the best hand protection solutions to our customers. Supported by a network of distribution centers in Europe, Mercator Medical is now one of the well-known suppliers of contamination prevention products in Europe.

Length (mm): 240mm
Colour: violet blue
Feature: non sterile, ambidextrous, beaded cuff
Surface: finger textured/palm textured
Packing: 100 pcs/10×100 pcs
Standards: ASTM D6319, EN 455, EN ISO 374, ISO 13485, ISO 9001

mCare


MERCATOR MEDICAL
NITRILE
mCare® | powder-free nitrile examination gloves
MERCATOR MEDICAL
mCare®
powder-free
nitrile examination gloves
Suitable for Food Contact


mCare® | powder-free nitrile examination gloves
NITRILE
Storage Instructions
It is recommended to store the gloves in dry place, in the temperature of 5-35°C and to protect them against direct sunlight and fluorescent light.
Recommended relative humidity in the room where the gloves are stored is 60 ±20%.
Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone.
Do not keep in direct vicinity of solvents, oils, fuels and lubricants.
Precautions and Indications for Use
Dry hands before putting the gloves on. Before usage, inspect the gloves for any defect or imperfections. Use at least 1 pair of gloves for one patient and one procedure, these are disposable gloves. Do not let chemical substances get under the gloves through the cuff. If a chemical substance reaches the skin, wash it away immediately with plenty of water with soap. If the gloves get punctured, torn or broken during their use, take them off and put on the new ones. Avoid using gloves dirty in the inside as they may cause irritation leading to skin inflammation or more serious damages. The gloves should not be used in contact with open fire and to protect against any sharp tools. The gloves are not intended for welding, electric shock protection, ionizing radiation or from the effect of hot or cold objects.
This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.
The chemical penetration resistance has been assessed under laboratory conditions from samples taken from the palm only (except in case where glove is equal to or over 400 mm – where the cuff is tested also) and relates only to the chemical tested and to the tested specimen. It can be different if the chemical is used in a mixture.
It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on the temperature, abrasion and degradation.
When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.
Gloves are suitable for special purposes as they are examination gloves where risk of injury to the wrist is considered to be minimal, gloves are shorter than EN 420 min. length requirement.
www.mercator.co.th
LOT PC000090320
02-2023
02-2020
AQL < 1.5
100 by weight
Mercator Medical (Thailand) Ltd.
88/8 Moo 12, Tambon Kampaengphet, Amphur Rattaphum, Songkhla 90180, Thailand
Made in Thailand / last rev. 06/2016
SATRA Technology Centre
Wyndham Way, Telford Way, Kettering, Northamptonshire NN16 8SD, United Kingdom
Notified body number 2777 CE
PAP


MERCATOR MEDICAL
mCare®
powder-free
nitrile examination gloves
EN 455 1/2/3/4


MERCATOR MEDICAL
expert in hand
protection solutions
CE FDA
mCare® | powder-free nitrile examination gloves


MERCATOR MEDICAL
NITRILE
XS (5-6)
S (6-7)
M (7-8)
L (8-9)
XL (9-10)
mCare®
powder-free
nitrile examination gloves


MERCATOR MEDICAL
HOSPITAL
DENTAL
LABORATORY
CLEANING
INDUSTRY
HOTEL
COSMETIC
FOOD
mCare®
powder-free
nitrile examination gloves
Suitable for Food Contact

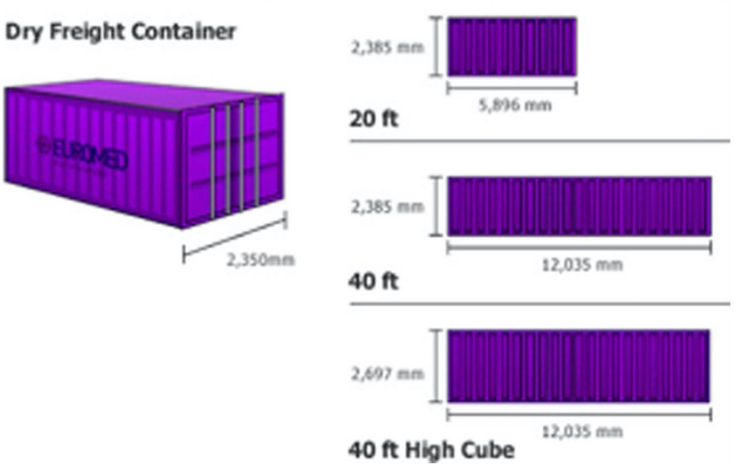
mCare


mCare


mCare


mCare
30°C
>70 %RH
5°C
21
PAP
nr
LOT PC000090320
02-2023
02-2020
MERCATOR MEDICAL (Thailand) Ltd.
88/8 Moo 12, Tambon Kampaengphet,
Amphur Rattaphum, Songkhla 90180, Thailand
XS (5-6)
S (6-7)
M (7-8)
L (8-9)
XL (9-10)

mCare



1,620 cartons/20'Dc

3,330 cartons/40'Dc

3,996 cartons/40'Hc

*** 1 carton = 5.6 kg ***

Total weight of the product /40'Hc = 22,377.6 kg

Certificate TH10/4860

The management system of

Mercator Medical (Thailand) Ltd.

88/8 Moo 12, Tambon Kampaengphet,
Amphur Rattaphum, Songkhla 90180, Thailand

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Manufacture of non-sterile powdered natural latex examination gloves
Manufacture of non-sterile powdered free natural latex examination gloves
Manufacture of non-sterile nitrile examination gloves
Distribution of natural latex and synthetic examination gloves

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organisation

This certificate is valid from 25 June 2016 until 25 June 2019 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 7 May 2019
Issue 6. Certified since 25 June 2010

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 9001 2015 0216

Certificate TH10/4859

The management system of

Mercator Medical (Thailand) Ltd.

88/8, 88/9 Moo 12, Tambon Kampaengphet,
Amphur Rattaphum, Songkhla 90180, Thailand

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Manufacture of non-sterile powdered natural latex examination gloves
Manufacture of non-sterile powder free natural latex examination gloves
Manufacture of non-sterile nitrile examination gloves
Distribution of natural latex and synthetic examination gloves

This certificate is valid from 28 June 2019 until 25 June 2022 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 07 May 2022
Issue 9. Certified since 25 June 2010

The audit leading to this certificate commenced on 10 May 2019
Previous issue certificate validity date was until 25 June 2019

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

Food and Drug Administration

Ministry of Public Health, Thailand

GMP CERTIFICATE

Ref. No. 1-1-04-02-14-00036

Valid until : 23 January 2017

It is hereby certified that

Mercator Medical (Thailand) Ltd.

88/8 Moo 12, Tumbon Kampaengphet,
Amphur Rattaphum, Songkhla 90180, THAILAND

is found to conform to the current Medical Device Good Manufacturing Practice 2005 laid down in accordance with the International Standard Requirements.

Scope : Manufacturing of non-sterile Examination Glove from Natural Rubber Latex

Issued on: 29 JUL 2014

.....

(Mr. [illegible])
Deputy Secretary General
Secretary-General
Food and Drug Administration

FOOD AND DRUG ADMINISTRATION

Certified since : 24 January 2011

Medical Device Control Division, Food and Drug Administration, Ministry of Public Health
88/24 Tiwanon Road, Nonthaburi 11000, Thailand
Tel.66 2590 7280,66 2590 7284 Fax.66 2590 7280

MERCATOR MEDICAL

EU DECLARATION OF CONFORMITY

Manufacturer' s Name : Mercator Medical (Thailand) Ltd.

Manufacturer' s Address : 88/8 Moo.12 Tambon Kampaengphet,
Amphur Rattaphum, Songkhla 90180 Thailand

Product : Non-sterile Powder Free Nitrile Latex Examination Gloves

We Mercator Medical (Thailand) Ltd. declare and ensure with sole responsibility, that the abovementioned product(s) meet the provision of the Council Directive 93/42/EEC (Medical Device Directive) Class I, Non-sterile, which apply to them, and are in conformity with the latest version of all parts of EN 455. The obligations laid down in Annex VII. And are in conformity with the provision of the PPE Regulation (EU) 2016/425 as a Category III product, Type B where such is the case, with the latest version of EN ISO 374-1, EN 374-2, EN 374-4, EN ISO 374-5, EN 16523-1, EN 388 and EN 420.

This declaration is supported by the Quality System approval to ISO13485:2016/EN ISO13485:2016 and ISO 9001:2015 issued by SGS United Kingdom Ltd Systems & Services Certification. All supporting documentation is retained at the premises of the manufacturer.

We explicitly authorize Mercator Medical S.A. to act as our sole Authorized Representative in European Union for the above indicate product.

Authorized Representative for Mercator Medical (Thailand) Ltd. is
Mercator Medical S.A.
Address: ul. H. Modrzejewskiej 30
31-327 Krakow, Poland

Authorized Signature:

Mr. Dariusz Jan Krezymon

CEO

Mercator Medical (Thailand)., Ltd

Date: 17/2/2020

U.S. FOOD & DRUG ADMINISTRATION

April 13, 2018

Mercator Medical (Thailand) LTD.
Dariusz Krezymon
Managing Director
88/2 Moo 12 Tambon Kampaengphet
Amphur Rattaphum, Thailand

Re: K172930
Trade/Device Name: mCare Powder-free Nitrile Blue Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: March 16, 2018
Received: March 23, 2018

Dear Dariusz Krezymon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172930

Device Name

mCare® Powder Free Nitrile Blue Examination Glove

Indications for Use *(Describe)*

mCare® Powder Free Nitrile Blue Examination Glove are disposable device intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

MERCATOR MEDICAL

510(k) SUMMARY

K172930

Powder Free Nitrile Blue Examination Gloves

1.0 Submitter :

Name : Dariusz Jan Krezymon (Mr.)

Address : Mercator Medical (Thailand) LTD.
88/8 Moo 12, Tambon Kampaengphet Amphur Rattaphum,
Songkhla 90180. Thailand

Phone Number :

Fax Number :

Date:

2.0 Name of Device :

mCare® Powder-free Nitrile Blue Examination Gloves

Common Name : Nitrile Blue Powder Free Examination Gloves

Classification Name : Patient Examination Gloves

3.0 Identification of The Legally Marketed Devices that equivalency is claimed:

MEDTEXX Blue Color Powder Free Nitrile Rubber Examination Gloves, 510(k): K022548

Regulatory Class I

Product Code : LZA

4.0 Description of The Device :

mCare® Powder-free Nitrile Blue Examination Gloves are substantially equivalent to the Class I patient examination gloves bearing the product code Nitrile - LZA (21CFR 880.6250).

They meet all the current specifications listed under the ASTM Specification D 6319 -10, Standard Specification for Nitrile Examination Gloves for Medical Application. They are made from acrylonitrile-butadiene copolymer dispersion.

These gloves are blue in color and are powder free.

5.0 Intended Use of the Device :

mCare® Powder-free Nitrile Blue Examination Gloves are disposable devices intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner.

6.0 Summary of the Technological Characteristics of the Device :

The mCare® Powder-free Nitrile Blue Examination Gloves, Non-Sterile are summarized with the following technological characteristics compared to ASTM D6319 or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate	Current
510(k) Number		K022548	K172930
Name of Device		Blue Powder Free Nitrile Patient Examination Glove	mCare® Powder-free Nitrile Blue Examination Gloves
Dimensions	ASTM D6319-10	Length min 230 mm. Width min 95 ± 10	Length min 230 mm. Width min 95 ± 10
Physical Properties	ASTM D6319-10	**Before Aging** Tensile Strength min 14 MPa Ultimate Elongation Min 500 % **After Aging** Tensile Strength min 14 MPa Ultimate Elongation Min 400 %	**Before Aging** Tensile Strength min 14 MPa Ultimate Elongation Min 500 % **After Aging** Tensile Strength min 14 MPa Ultimate Elongation Min 400 %
Thickness	ASTM D6319-10	Finger min 0.05 mm. Palm min 0.05 mm.	Finger min 0.05 mm. Palm min 0.05 mm.
Powder Free	ASTM D6319-06	≤ 2 mg/glove	≤ 2 mg/glove
Biocompatibility	Primary Skin Irritation - ISO 10993-10:2010 (E) & Consumer Product Safety Commission, Tittle 16, Chapter II, Part 1500	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant
	Dermal Sensitization – ISO 10993-10:2010 (E) & Consumer Product Safety Commission, Tittle 16, Chapter II, Part 1500.3(c) (4)	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer

MERCATOR MEDICAL

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate	Current
Watertight (1000 ml.)	ASTM D6319-06	AQL 2.5	AQL 2.5
Intended use	-	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
Material	ASTM D6319-10	Nitrile	Nitrile
Color	-	Blue	Blue
Texture	-	Finger texture	Finger texture
Size	Medical Glove Guidance Manual -Labeling	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large
Single Use	Medical Glove Guidance Manual -Labeling	Single Use	Single Use
Manufacturer(s)	-	LATEXX Manufacturing,	Mercator Medical (Thailand) LTD.
Conclusion			Similar

There are no significant differences between the two products and are identical in terms of intended use, materials, design, manufacturing methods its meets the ASTM standards.

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above (ASTM Requirements).

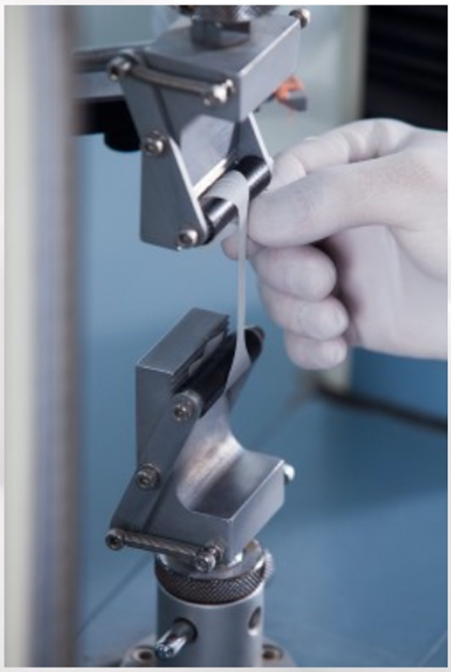
8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Not applicable – Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

9.0 Conclusion

mCare® Powder-free Nitrile Blue Examination Gloves performs according to the gloves performance standards referenced in section 6.0 above and meet ASTM standards. Consequently, the device is as safe and as effective and performs as well as or better than the predicate device.

Quality Assurance



Mercator Medical Thailand provides products of the highest quality. The company maintains stringent quality assurance and control standards throughout the production process in order to ensure a consistent quality level of its products. Every single production stage is carefully controlled. The state-of-the-art plant has a modern testing laboratory that is well equipped to conduct all the required physical and chemical tests on raw materials, semi-finished materials and finished products, thus ensuring that products conform to all the necessary quality and performance standards.

All our gloves comply with all the technical and performance requirements of international standards (ASTM D3578, EN 455), and our manufacturing facilities' quality system is certified to ISO 9001 and ISO 13485 quality management systems standards. Our products hold the necessary US FDA 510 (k) registration for importation into the United States of America and are CE certified for sale in the European Union.

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User instruction

The instruction below should be used in conjunction with detailed information on the packaging.

Short description of the product

Nitrile examination and protective gloves, powder-free, non-sterile for disposable use

Full description of the product

Raw material	: nitrile
External surface	: fingertip/pam textured, polymerized
Internal surface	: polymerized + chlorinated
Cuff	: beaded
Colour	: blue/white/violet blue/black/cobalt
Shape	: ambidextrous, fitting to the right and left hand
Size range	: XS (5-6), S (6-7), M (7-8), L (8-9), XL (9-10), XXL (10-11)
AQL	: 1.5
Quantity in packaging	: 50/100/200 pcs. by weight
Shelf life	: 3 years (from the date of manufacturing)

Storage instructions

It is recommended to store the gloves in dry place, in the temperature of 5-35°C and to protect them against direct sunlight and fluorescent light. Recommended relative humidity in the room where the gloves are stored is 60 ±20%.

Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone.

Do not keep in direct vicinity of solvents, oils, fuels and lubricants.

Food contact

Gloves are marked with food contact symbol and comply with the requirements of Regulation (EU) No 10/2011, European Regulation (EC) No 1935/2004 and with Regulation (EC) No 2023/2006 on Good Manufacturing Practice. Gloves are suitable for handling any type of food and have been tested for Overall Migration Test acc. EN 1186:

Extraction conditions (tested for 1 h in 40°C)	Analysis results [mg/dm²]	Test Result (limit < 10 mg/dm²)
50% ethanol	3	Pass
3% acetic acid	<3	Pass
10% Ethanol	<3	Pass
Isooctane	<3	Pass

MDD classification & compliance

Gloves are classified as class I Medical Device as per Annex IX of the Council Directive 93/42/EEC and comply to standards:
EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008+A1:2013.

PPE classification & compliance

Gloves are category III Personal Protective Equipment as per Annex I of the Regulation 2016/425 and comply to standards:
EN 420:2003+A1:2009, EN ISO 374-1:2016 (Type B), EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016.

EU Type Examination Certificate issued by: SATRA (Notified Body No. 2777)

Checking of PPE manufactured:
CE 2777
SATRA Technology Europe Limited.
Bracetown Business Park.
Clonee.
D15YN2P.
Republic of Ireland.

Declaration of Conformity is available at www.mercator.co.th

Intended use

These are non-sterile examination and protective gloves for single use, intended for use in medical field to: protect patient and user from cross-contamination, conducting medical examinations, diagnostic and therapeutic procedures and for handling medical contaminated material. Gloves are classified as Medical Devices Class I and as a Personal Protective Equipment category III. Their design and labelling correspond to the requirements of the European Medical Device Directive 93/42/EEC and the European Regulation 2016/425 on Personal Protective Equipment. Gloves should be used solely according to their intended application.

Precautions and indications for use

Dry hands before putting the gloves on. Before usage, inspect the gloves for any defect or imperfections. Use at least 1 pair of gloves for one patient and one procedure, these are disposable gloves. Do not let chemical substances get under the gloves through the cuff. If a chemical substance reaches the skin, wash it away immediately with plenty of water with soap. If the gloves get punctured, torn or broken during their use, take them off and put on the new ones. Avoid using gloves dirty in the inside as they may cause irritation leading to skin inflammation or more serious damages. The gloves should not be used in contact with open fire and to protect against any sharp tools. The gloves are not intended for welding, electric shock protection, ionizing radiation or from the effect of hot or cold objects.

This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.

The chemical penetration resistance has been assessed under laboratory conditions from samples taken from the palm only (except in case where glove is equal to or over 400 mm – where the cuff is tested also) and relates only to the chemical tested and to the tested specimen. It can be different if the chemical is used in a mixture.

It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on the temperature, abrasion and degradation.

When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.

Gloves are suitable for special purposes as they are examination gloves where risk of injury to the wrist is considered to be minimal, gloves are shorter than EN 420 min. length requirement.

Components / hazardous components

Some gloves may contain components known to be a possible cause of allergy for person allergic to them, who may develop contact irritation and/or allergic reaction. In case of an allergic reaction, seek medical assistance immediately.

Disposal

Used gloves can be contaminated with contagious or other hazardous substances. They should be disposed of in accordance with local regulation. Gloves should be buried or burned under controlled conditions.

Manufacturer

MERCATOR MEDICAL (Thailand)Ltd.
88/8 Moo 12 Tambon Kampaengphet,
Amphur Rattaphum,Songkhla 90180,Thailand.
www.mercator.co.th

MERCATOR MEDICAL

Permeation performance levels as per EN ISO 347-1:2016 Level1>10min , Level2>30 min, level3>60 min, level4>120min,Level5>240min, Level6>480min		EN 374-4:2013 Degradation [%]
Test results acc. to EN 16523-1:2015		
Chemical	Level	
35% Ethanol	6	55.0
40% Isopropanol	6	68.7
10 Acetic acid	4	53.7
50 % Benzalkonium chloride*	6	29.5
4% Chlorhexidine digluconate **	6	32.9
10% Phosphoric acid	6	14.0
40 % Sodium hydroxide	6	2.6
12 % Sodium hypochlorite	6	22.7
50% Sulphuric Acid	6	21.1
5% Ethidium Bromide	6	32.9
3% Hydrogen peroxide	6	44.0
30% Hydrogen peroxide	2	52.8
37% Formaldehyde	5	20.0
50% Glutaraldehyde	6	22.9
0.1% Phenol	6	24.7

- Permeation rate 7 g/cm2 /min,EN374-4:2013 degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

** Permeation rate 7 g/cm2 /min,EN374-4:2013 degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

Noted : 1) Glove minimum length for Lab application accordance to EN455-2

Test acc. To EN 374-2:2014 – Level 2 (ISO 2859)	
Performance level	AQL
Level 3	< 0.65
Level 2	<1.5
Level 1	< 4.0

Test acc. To EN ISO 374-5:2016	
Protection against bacteria & fungi	Pass
Protection against viruses	Pass

Symbols used on the packaging


Do not re-use / gloves are intended for single use

Non-sterile gloves


Powderfree gloves


Do not use, if package is damaged


Keep away from solar and fluorescent light


Keep away from moisture, store in a dry place

Temperature limitation / gloves store in temperature 5-35°C

Keep away from ozone

Catalogue number

Lot / batch number

100 gloves by weight

EC Rep symbol should be used with name and address of EC representative

Package made from paper, qualify for recycling


Protection against bacteria, fungi and viruses


Gloves protecting against chemical dangers with digit literal codes


Package is treated as municipal waste


Manufacturer, symbol should be accompanied by name and address of Manufacturer


Date of manufacture


Food contact symbol (article is suitable for food contact, for details check the instruction for use)


Expiry date


Protective glove against mechanical risk (if applicable accompanied by 4-digit code of relevant performance levels)


Consult instructions for use

HOW TO PUT THE GLOVES ON?

Take one glove from the box pulling by the cuff.

Hold the glove by the cuff with the same hand you used to pull it from the box and put the other hand into the glove without touching the working surface.

Stretch the glove on the right hand.

Take another glove from the box with the hand wearing a glove.

Put the glove on the hand and smooth it out.

Done!

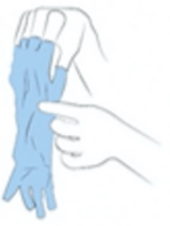
HOW TO TAKE THE GLOVES OFF?

Hold the glove with a finger of the other hand at the cuff.

Slide the glove down to mid-palm.

Hold the other glove by its outer edge.

When removing the gloves, turn them inside out.



Hold both gloves without touching the contaminated walls.

Removed gloves should be treated as healthcare waste.

mCare

SATRA TECHNOLOGY

Issued to:

Mercator Medical (Thailand) Ltd.
88/8 Moo 12, Tambon Kampaengphet,
Amphur Rattaphum,
Songkhla
90180
Thailand

Notified Body: 2777

SATRA customer number: P0912

EU Type-Examination Certificate

Certificate number: 2777/11283-02/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

8PF1

Sizes:
6 (XS)
7 (S)
8 (M)
9 (L)
10 (XL)
11 (XXL)

Description:

Powder free, nitrile examination gloves with textured fingers

Classification:

EN ISO 374-1:2016 Type B	Level	EN 374-4:2013
N-heptane (J)	1	40.9%
Sodium hydroxide 40% (K)	6	-39.8%
Hydrogen peroxide 30% (P)	2	27.1%
Formaldehyde 37% (T)	6	-19.7%

EN ISO 374-5:2016	
Protection against bacteria and fungi	PASS
Protection against viruses	Not tested

Standards/Technical specifications applied:
EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016; EN 420: 2003+A1: 2009

Technical reports/Approval documents:
CHM0274463/1833/JS/A/Issue 2, CHM0274463/1833/JS/B/Issue 2, CHM0274463 /1833 /SPT /1, DPL/PTL/071 (01), DPL/PTL/071 (02), DPL/PTL/071 (03), SPC0206655/1232/MB, SPC0206655/1232/ Issue 4; SPC0261861 /1736

Signed on behalf of SATRA:

Besjana Pilinci

Pete Doughty

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