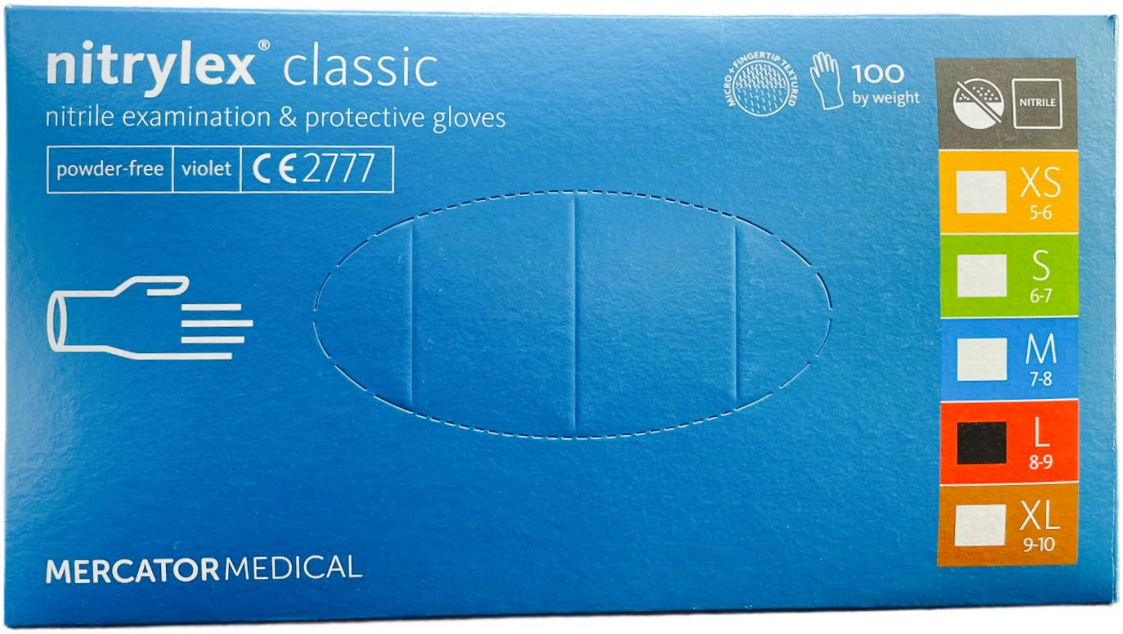
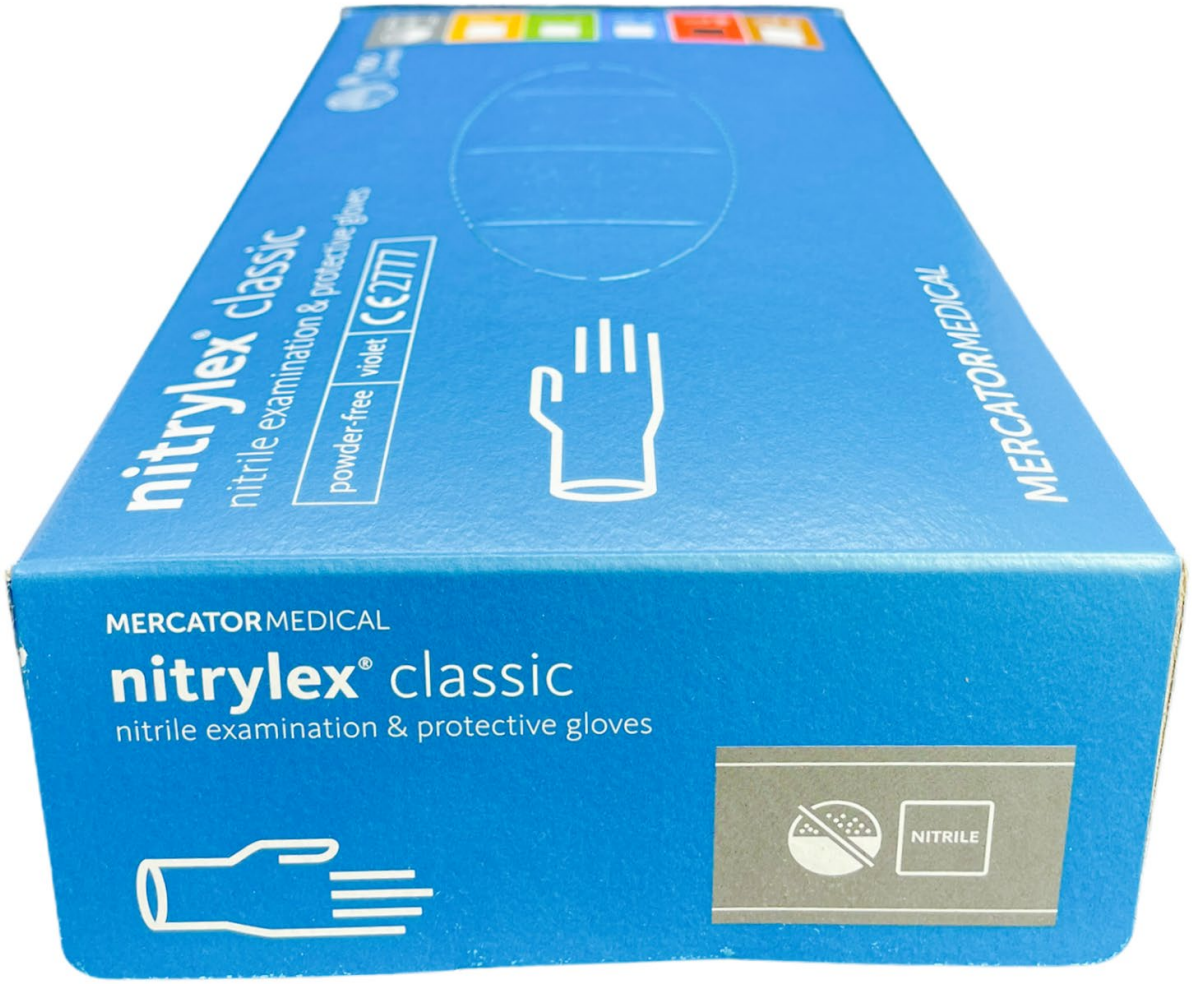

nitrylex® classic
nitrile examination & protective gloves
powder-free
violet
CE 2777
100
by weight
NITRILE
XS
5-6
S
6-7
M
7-8
L
8-9
XL
9-10
MERCATOR MEDICAL


nitrylex® classic
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CE 2777
MERCATOR MEDICAL
MERCATOR MEDICAL
nitrylex® classic
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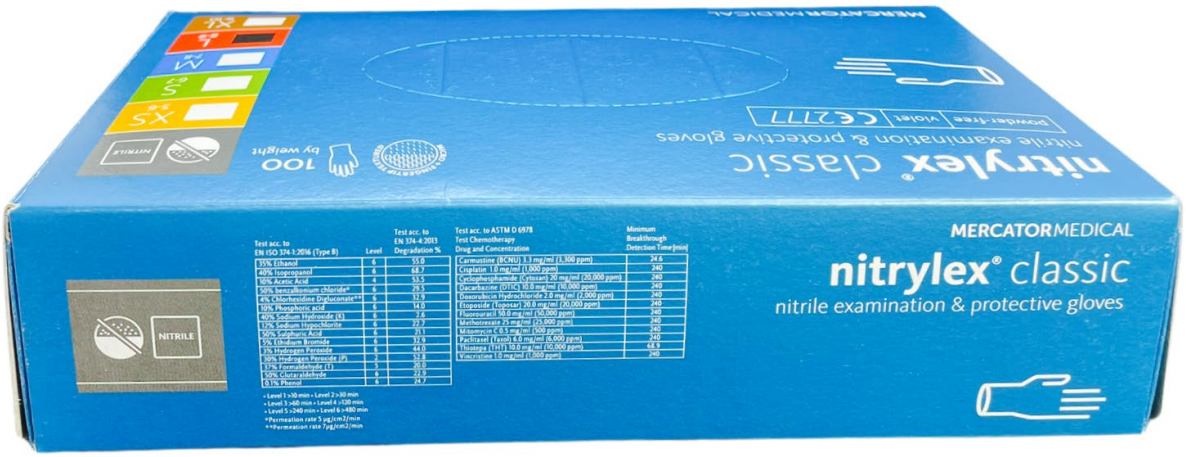
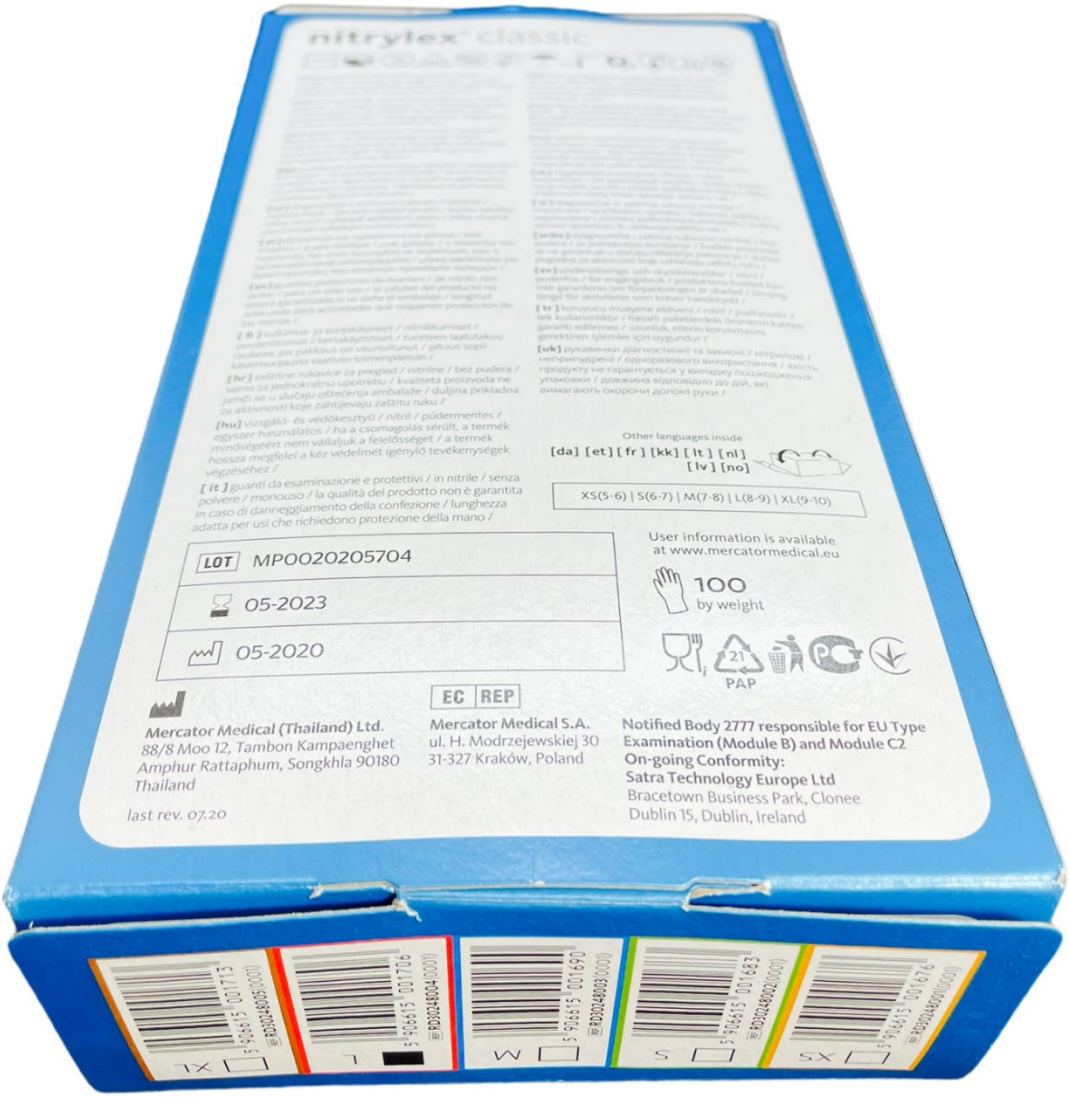
NITRILE


MERCATOR MEDICAL
nitrylex® classic
nitrile examination & protective gloves
Powder-free Violet CE 2777
100 by weight
NITRILE
Test acc. to EN ISO 374-1:2016 (Type B)
Test acc. to EN 374-4:2013
Test acc. to ASTM D 6978
Minimum Breakthrough Detection Time [min]


Other languages inside
[da] [et] [fr] [kk] [lt] [nl] [lv] [no]
XS(5-6) | S(6-7) | M(7-8) | L(8-9) | XL(9-10)
User information is available at www.mercatormedical.eu
100 by weight
PAP
LOT MP0020205704
05-2023
05-2020
Mercator Medical (Thailand) Ltd.
88/8 Moo 12, Tambon Kampaenghet
Amphur Rattaphum, Songkhla 90180
Thailand
last rev. 07.20
EC REP
Mercator Medical S.A.
ul. H. Modrzejewskiej 30
31-327 Kraków, Poland
Notified Body 2777 responsible for EU Type Examination (Module B) and Module C2
On-going Conformity:
Satra Technology Europe Ltd
Bracetown Business Park, Clonee
Dublin 15, Dublin, Ireland

MERCATOR MEDICAL

DEKLARACJA ZGODNOŚCI UE

Wytwórca: **MERCATOR MEDICAL S.A.**
UL. H.MODRZEJEWSKIEJ 30
31-327 KRAKÓW, POLSKA

Deklaruje na swoją wyłączną odpowiedzialność, że niesterylne rękawice diagnostyczne i ochronne:

Nazwa produktu	Opis produktu	Rozmiar	Nr referencyjne
nitrylex® classic	nitrylowe, bezpudrowe, w kolorze niebieskim, do jednorazowego użytku	XS (5-6) - XL (9-10)	a'100: RD30019001-05 a'200: RD30096001-05
	nitrylowe, bezpudrowe, w kolorze białym, do jednorazowego użytku	XS (5-6) - XL (9-10)	a'50: RD30174001-05 a'100: RD30143001-05 a'200: RD30097001-05
	nitrylowe, bezpudrowe, w kolorze fioletowym, do jednorazowego użytku	XS (5-6) - XL (9-10)	a'100: RD30169001-05 a'200: RD30168001-05

zaklasyfikowane jako wyrób medyczny klasy I zgodnie z Załącznikiem IX Dyrektywy Rady 93/42/EWG (Rozporządzeniem Ministra Zdrowia z dnia 5 listopada 2010 r. w sprawie sposobu klasyfikowania wyrobów medycznych) spełniają wymagania zasadnicze Dyrektywy Rady 93/42/EWG znowelizowanej Dyrektywą 2007/47/WE (Ustawy z dnia 20 maja 2010 roku o wyrobach medycznych) oraz są zgodne z europejskimi zharmonizowanymi normami: EN 455, EN ISO 15223-1, EN 1041. Procedura oceny zgodności wyrobów przeprowadzona zgodnie z Załącznikiem I oraz Załącznikiem VII Dyrektywy Rady 93/42/EWG (Rozporządzenia Ministra Zdrowia z dnia 17 lutego 2016 r. w sprawie wymagań zasadniczych oraz procedur oceny zgodności wyrobów medycznych).

Wyżej opisane produkty zaklasyfikowane zostały również jako Środek Ochrony Indywidualnej kategorii III i są zgodne z Rozporządzeniem Parlamentu Europejskiego i Rady (UE) 2016/425 z dnia 9 marca 2016 r. w sprawie środków ochrony indywidualnej oraz uchylenia dyrektywy Rady 89/686/EWG oraz europejskimi normami: EN 420:2003+A1:2009, EN ISO 374-1:2016, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016.

Wyżej opisane produkty są identyczne ze Środkiem Ochrony Indywidualnej, który jest przedmiotem badania typu UE (Moduł B) oraz certyfikatu badania typu UE o nr 2777/10015-03/E17-01 wydanego przez jednostkę notyfikowaną:

Satra Technology Europe Limited (2777)
Bracetown Business Park, Clonee, Dublin 15, Dublin, Irlandia

oraz podlegają procedurze oceny zgodności z typem w oparciu o wewnętrzną kontrolę produkcji oraz nadzorowane kontrole produktu w losowych odstępach czasu (Moduł C2), pod nadzorem jednostki notyfikowanej:

Satra Technology Europe Limited (2777)
Bracetown Business Park, Clonee, Dublin 15, Dublin, Irlandia

Data i miejsce wydania:
30.09.2019, Kraków

Podpis w imieniu Wytwórcy:

Wojciech Hercka
Kierownik Dokumentacji Produktowej

MERCATOR MEDICAL S.A.
ul. Heleny Modrzejewskiej 30, 31-327 Kraków
tel. 12 66 55 400, fax 12 66 55 415
Rejestracja: Sąd Rejonowy dla Krakowa - Śródmieścia w Krakowie,
XI Wydział Gospodarczy KRS, KRS: 0000036244
Kapitał zakładowy (w całości wpłacony): 10.589.100 PLN
NIP: 677-10-36-424, REGON: 350967107
Numer BDO: 000056063

MERCATOR MEDICAL

nitrylex® classic

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	: bisque with fingertip textured, polymerized
Internal surface	: polymerized + chlorinated
Cuff	: beaded
Colour	: blue/white/violet
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)
AQL	: 1.0
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 2 h in 40°C)	Analysis results [mg/dm²]	Test Result (limit < 10 mg/dm²)
3% acetic acid	1,1	Pass
10% ethanol	<1	Pass
Olive oil	<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.

Declaration of Conformity can be found under below web address:
http://mercatormedical.eu/produkty/rekawice/diagnostyczne/nitrylex-classic

Notified Body 2777 responsible for EU Type Examination (Module B) and Module C2 On-going Conformity:
Satra Technology Europe Ltd
Bracetown Business Park, Clonee
Dublin 15, Dublin, Ireland

CE 2777

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 corresponds 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 S.A.
ul. H. Modrzejewskiej 30
31-327 Cracow, Poland
www.mercatormedical.eu

Permeation performance levels as per EN ISO 374-1:2016					
• Level 1 > 10 min • Level 2 > 30 min • Level 3 > 60 min • Level 4 > 120 min • Level 5 > 240 min • Level 6 > 480 min					
Test results acc. to EN 16523-1:2015		EN 374-4:2013	Test results acc. to EN 16523-1:2015		EN 374-4:2013
Chemical	Level	Degradation [%]	Chemical	Level	Degradation [%]
*4% Chlorhexidine Digluconate	6	19.0	30% Hydrogen Peroxide (P)	2	22.8
40% Sodium Hydroxide (K)	6	-42.9	1.5% Methanol in water	6	21.9
10-13% Sodium Hypochlorite	6	14.7	25% Ammonium Hydroxide (O)	1	-52.0
50% Sulphuric Acid	6	-20.5	3% Povidione-iodine	6	33.7
10% Acetic Acid	4	66.7	10% Sodium Percarbonate	6	15.4
5% Ethidium Bromide	6	3.4	50% Glutaraldehyde	6	27.4
37% Formaldehyde (T)	3	5.0	0.1% Phenol	6	33.8

*Permeation rate 7µg/cm²/min, EN 374-4:2013 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

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	Non-sterile gloves		Powdered gloves
	Do not use, if package is damaged		Keep away from solar and fluorescent light		Powder free gloves
	Keep away from moisture, store in a dry place	35°C 5°C	Temperature limitation / gloves store in temperature 5-35°C	POLYMER COATED	Presence of polymer coating on the inner surface of the glove
LATEX	Raw material – natural rubber latex	O_3	Keep away from ozone	COSMETIC COATING	Presence of cosmetic coating on the inner surface of glove
REF	Catalogue number	LOT	Lot / batch number	SINGLET OXYGEN $1O_2$	Gloves with incorporated singlet oxygene layer.
EC REP	EU Authorized Representative, symbol should be accompanied by name and address of Authorized Representative		Expiry date	TEXTURED	Presence of external texture on the glove
ISO 374-5:2016	Marking of gloves protecting against bacteria and fungi.		Gloves protecting against chemical dangers with digit literal odes	NITRYL	Gloves made from nitrile
ISO 374-5:2016 VIRUS	Marking of gloves protecting against viruses, bacteria and fungi.		Antistatic gloves	VINYL	Gloves made from vinyl
ISO 374-1:2016/Type A	Marking o type A chemical resistant gloves. Six tested chemicals shall be identified by their code letter under pictogram.		Date of manufacture	NEOPREN	Gloves made from neoprene
UVWXYZ ISO 374-1:2016/Type B	Marking o type B chemical resistant gloves. Three tested chemicals shall be identified by their code letter under pictogram.		Manufacturer, symbol should be accompanied by name and address of Manufacturer	POLIIZOPREN	Gloves made from polyisoprene
XYZ ISO 374-1:2016/Type C	Marking o type C chemical resistant gloves. One tested chemicals shall be identified by their code letter under pictogram.		Consult instructions for use	50 by weight	50 gloves by weight
	Protective glove against mechanical risk (if applicable accompanied by 4 digit code of relevant performance levels)	21 PAP	Package made from paper, qualify for recycling	100 by weight	100 gloves by weight
	Food contact symbol (article is suitable for food contact, for details check the instruction for use)		Package is treated as municipal waste	200 by weight	200 gloves by weight
	Indicates compliance with the requirements of Russian market		Indicates compliance with the requirements of Ukrainian market		Additonal information on inner side of package

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.

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
11643-2017-CE-POL-NA-PS	PRJC-84149-2017-PRC-POL	27 May 2024

This is to certify that the quality system of:

Mercator Medical S.A.

ul. H. Modrzejewskiej 30
31-327 Kraków, Poland

For design, production and final product inspection/testing of:
EXAMINATION & PROTECTIVE NON-STERILE POWDER-FREE GLOVES

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 20 November 2017

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Cathrine Wisbech

Cathrine Wisbech

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

Certificate No.:
11643-2017-CE-POL-NA-PS

Project No.:
PRJC-84149-2017-PRC-POL

Valid Until:
27 May 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	20 November 2017

Products covered by this Certificate:

Product Description	Product Name	Class
Examination & Protective Gloves - Non-Sterile - Powder-Free	**Nitrylex® Classic -Non-Sterile -Powder-Free** Raw material: nitrile Colour: blue, purple, white Sizes: XS, S, M, L, XL	Ia
Examination & Protective Gloves - Non-Sterile - Powder-Free	**Nitrylex® Green -Non-Sterile -Powder-Free** Raw material: nitrile Colour: mint Sizes: XS, S, M, L, XL	Ia

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Mercator Medical S.A.	ul. H. Modrzejewskiej 30 31-327 Kraków, Poland

Certificate No.:	Project No.:	Valid Until:
11643-2017-CE-POL-NA-PS	PRJC-84149-2017-PRC-POL	27 May 2024

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate