MERCATOR MEDICAL

EU DECLARATION OF CONFORMITY

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

Declares under its sole responsibility that non-sterile examination and protective gloves:

Brand	Type	Sizes	Reference Numbers
nitrylex® classic	nitrile, powder-free, blue, for single use	XS (5-6) - XL (9-10)	a'100: RD30019001-05 a'200: RD30096001-05
	nitrile, powder-free, white, for single use	XS (5-6) - XL (9-10)	a'50: RD30174001-05 a'100: RD30143001-05 a'200: RD30097001-05
	nitrile, powder-free, violet, for single use	XS (5-6) - XL (9-10)	a'100: RD30169001-05 a'200: RD30168001-05
Basic UDI-DI: 5906615 RD NS N PF 9C			

meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices, are classified as medical device class I according to Annex VIII of the Regulation (EU) 2017/745 and comply with European harmonized standards: EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008.

The products described above are also classified as Personal Protective Equipment Category III and comply with Regulation (EU) 2016/425 of the European Parliament and the Council of 9 March 2016 on Personal Protective Equipment and resolution of the Council Directive 89/686/EEC and European standards: 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.

The products described above are identical to the Personal Protective Equipment, which is the subject to the EU Type Examination (Module B) under certificate No. 2777/10015-03/E17-01 issued by notified body:

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

and are subject to the conformity to type procedure based on the internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body:

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

Date and place of issue:
05.05.2020, Kraków

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

Signed on the behalf of the Manufacturer:

Wojciech Hercka
Product Documentation Manager

MERCATORMEDICAL

DECLARATION OF CONFORMITY

Manufacturer: **MERCATOR MEDICAL S.A.**
UL. H.MODRZEJEWSKIEJ 30
31-327 KRAKOW, POLAND

declares that the following product:

nitrylex® classic
powder free nitrile examination gloves, non-sterile

is in conformity with the requirements stated in **Regulation (EC) No 1935/2004** on materials and articles intended to come into contact with food and **Commission Regulation (EU) No 10/2011** on plastic materials and articles intended to come into contact with food.
Manufacturing process of this product is in compliance with requirements of Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Issue Date: 23.05.2017

MERCATOR MEDICAL
Spółka Akcyjna
ul. Heleny Modrzejewskiej 30
31-327 Kraków
tel. +48 12 66 55 400, fax +48 12 66 55 415
-6-

Sign on behalf of the Manufacturer

Wojciech Hercka
Technical Documentation Specialist

Issued to:

Mercator Medical S.A.
Ul. H. Modrzejewskiej 30
31-327 Krakow
Poland

Notified Body: 2777

SATRA customer number: P1343

EU Type-Examination Certificate

Certificate number: 2777/10015-03/E17-01

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
Nitrylex classic
Nitrylex one by one

Sizes: 5/6 (XS) to 9/10 (XL)

Description
Disposable powder free nitrile glove available in white, blue and violet blue. Non-Sterile

Classification:

EN ISO 374-1:2016 (Type B)	**Level**	**EN374-4:2013 Degradation %**
*4% Chlorhexidine Digluconate	6	19.0
40% Sodium Hydroxide (K)	6	-42.9
10-13% Sodium Hypochlorite	6	14.7
50% Sulphuric Acid	6	-20.5
10% Acetic Acid	4	66.7
5% Ethidium Bromide	6	3.4
37% Formaldehyde (T)	3	5.0
50% Glutaraldehyde	6	27.4
0.1% Phenol	6	33.8
30% Hydrogen Peroxide (P)	2	22.8
1.5% Methanol in water	6	21.9
25% Ammonium Hydroxide (O)	1	-52.0
3% Povidone-iodine	6	33.7
10% Sodium Percarbonate	6	15.4
* Permeation rate 7µg/cm^2/min		
EN ISO 374-5: 2016		
Protection against Bacteria & Fungi	Pass	
Protection against viruses	Pass	

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

Technical reports/Approval documents:
SATRA: SPC0216113/1327/SMcD/RS, SPC0216113/1327, PRC0250570/1640/SPT, CHM0248297/1630/EN/E, CHM0248297/1630/EN/D/Issue 2, CHM0257198/1719/SMcD/A, CHM0257198/1719/SMcD/B, CHM0257198/1719/SMcD/C, CHM0257198/1719/SMcD/D

Signed on behalf of SATRA: Hannah Coe Jacque Glasspool

Date of issue: **18/09/2019** **Expiry date:** **21/04/2023**

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity.

Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.

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

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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 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	Temperature limitation / gloves store in temperature 5-35°C	Presence of polymer coating on the inner surface of the glove
Raw material – natural rubber latex	Keep away from ozone	Presence of cosmetic coating on the inner surface of glove
Catalogue number	Lot / batch number	Gloves with incorporated singlet oxygene layer.
EU Authorized Representative, symbol should be accompanied by name and address of Authorized Representative	Expiry date	Presence of external texture on the glove
Marking of gloves protecting against bacteria and fungi.	Gloves protecting against chemical dangers with digit literal odes	Gloves made from nitrile
Marking of gloves protecting against viruses, bacteria and fungi.	Antistatic gloves	Gloves made from vinyl
Marking o type A chemical resistant gloves. Six tested chemicals shall be identified by their code letter under pictogram.	Date of manufacture	Gloves made from neoprene
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	Gloves made from polyisoprene
Marking o type C chemical resistant gloves. One tested chemicals shall be identified by their code letter under pictogram.	Consult instructions for use	50 gloves by weight
Protective glove against mechanical risk (if applicable accompanied by 4 digit code of relevant performance levels)	Package made from paper, qualify for recycling	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 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

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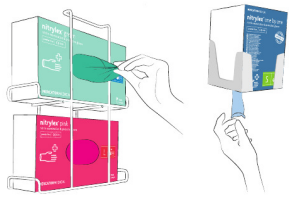
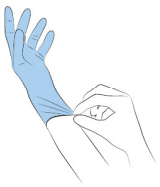
HOW TO PUT THE GLOVES ON?



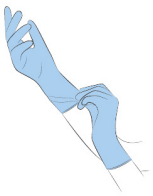
Take one glove from the box pulling by the cuff.

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.

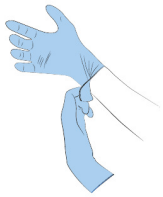
Take another glove from the box with the hand wearing a glove.



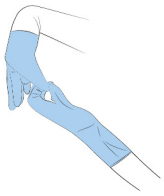
Put the glove on the hand and smooth it out.

Done!

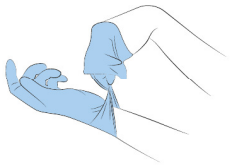
HOW TO TAKE THE GLOVES OFF?



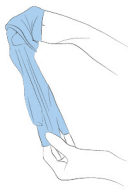
Hold the glove with a finger of the other hand at the cuff.



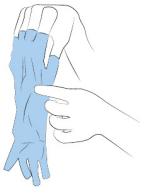
Slide the glove down to mid-palm.



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.

Technical Data Sheet

nitrylex® classic violet

PRODUCT DESCRIPTION

Type of the glove	Non-sterile, powder free, examination and protective glove for single use
Material	Nitrile
Donning powder	-
Colour	Violet Blue
Shape	Ambidextrous
Cuff	Beaded
External surface	Finger Textured 35 mm. From Tip
Internal surface	Polymerized + chlorinated
Packaging	10 x 100 pcs

PRODUCT REFERENCES

SIZE / REFERENCE NUMBER	
XS	RD30248001
S	RD30248002
M	RD30248003
L	RD30248004
XL	RD30248005

PHYSICAL PROPERTIES

Dimensions	Size	XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)
Length [mm] Minimum		240	240	240	240	240
Width [mm]		<80	80 ±10	95 ±10	110 ±10	≥110
Thickness (single wall) [mm] Minimum	Finger			0,08		
	Palm			0,06		
	Cuff			0,05		
Elongation at break [%] Minimum	Before ageing	500 (ISO 11193-1)				
	After ageing	400 (ISO 11193-1)				
Force at break[N] Minimum	Before ageing	6,0 (EN 455-2) / 7,0(ISO 11193-1)				
	After ageing	6,0 (EN 455-2) / 6,0(ISO 11193-1)				

MANUFACTURING AND SAFETY STANDARDS

AQL	Manufacturing final release: G-I inspection level AQL 1.5 in accordance with ISO 2859-1	
Powder content	< 2 mg/glove	
Protein content	N/A	
CE classification	Class I - Medical Device Regulation (EU) 2017/745	Category III – Personal Protective Equipment (Regulation (EU) 2016/425)
Compliances	EN 455-1, EN 455-2, EN 455-3, EN 455-4 EN ISO 15223-1 EN 1041 ISO 11193-1 EN ISO 13485	EN ISO 374-1 (Type B), EN 374-2, EN 374-4, EN ISO 374-5 EN 16523-1 EN 420
Viral test	Test in accordance with ASTM F1671 & ISO 16604	
Cytostatics permeation	Test in accordance with ASTM D6978	
Chemical substances permeation	Test in accordance with EN 16523-1	
Food contact	Declaration of conformity for food contact in accordance with Regulation (EC) No 1935/2004 and Overall Migration Test in accordance with European Commission Directive 93/11/EEC and Council of Europe Resolution AP (2004) 4	
Shelf life	3 years	

STORAGE

Storage instruction	Keep out of direct sunlight. Store in a cool, dry place in temperature 5-35° C. Keep away from sources of ozone and ignition.

Issue date: 11.08.2020

Prepared by: Kanokwan Saleeon – Assistant Regulatory Compliance Manager
Approved by: Phaitoon Intharat – QA Manager