MERCATOR

EU DECLARATION OF CONFORMITY

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

SRN: PL-MF-000018942

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

Brand	Type	Sizes	Reference numbers
MERCATOR hybrid +	synthetic vinyl, powder free, blue, for single use	S (7) - XL (10)	a'100: RD20259002-05_0991
	synthetic vinyl, powder free, violet, for single use	S (7) - XL (10)	a'100: RD20262002-05_0991
	synthetic vinyl, powder free, black, for single use	S (7) - XL (10)	a'100: RD20263002-05_0991
Basic UDI-DI: 5906615 RD NS V PF AL			
Intended use: non-sterile examination and protective gloves, for single use			

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, rule 5, according to Annex VIII of the Regulation (EU) 2017/745 and comply with European standards: EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN 1041:2008+A1:2013.

The products described above are 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 ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016.

The products described above are subject to the EU Type Examination (Module B) under certificate No. 2777/15276-01/E02-01 issued by notified body:

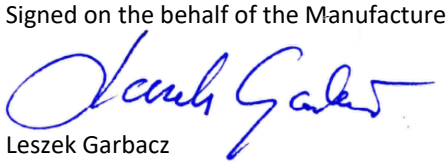
Satra Technology Europe Limited (2777)
Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

and are subject to the conformity assessment procedure based on quality assurance of the production process (Module D) under surveillance of the notified body:

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

Date and place of issue:
20.07.2022, Kraków

Signed on the behalf of the Manufacturer:



Leszek Garbacz
Product Documentation Manager

Rev.1.1

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INSTRUCTION FOR USE OF PERSONAL PROTECTIVE EQUIPMENT

MERCATOR hybrid+

RD20259002-05(0991)

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

Short description of the product

Examination and protective gloves, synthetic vinyl, powder-free, for single use, non-sterile

Full description of the product

Reference number	: RD20259002-05(0991)
Raw material	: polyvinyl chloride
Cuff	: beaded
Colour	: blue
Shape	: ambidextrous, fitting to the right and left hand
Size range	: S (7), M (8), L (9), XL (10)
AQL	: 1.5
Quantity in packaging	: 100 pcs. by weight
Shelf life	: 3 or 5 years depends on LOT number (check the packaging)

Storage instructions

It is recommended to store the gloves in dry place, in the temperature of 10-30°C and to protect them against direct sunlight.
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 the food, except for fatty foods, and have been tested for Overall Migration Test acc. EN 1186.

MD classification & compliance

Gloves are classified as class I according to Annex VIII of the Regulation (EU) 2017/745 and comply to standards:

EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, 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 ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016.

Notified Body responsible for EU Type Examination (Module B) and on-going conformity (Module D):

Satra Technology Europe Ltd
Bracetown Business Park,
Clonee, Dublin 15,
Dublin, Ireland

CE 2777

Declaration of Conformity and this instruction for use available under below web address:
https://mercatormedical.eu

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, type B. Gloves designed to protect against substances and mixtures which are hazardous to health and against harmful biological agents. Gloves designed to protect against to chemical risk according with EN ISO 374-1:2016+A1:2018 and microorganism (viruses, bacteria and fungi) risks according with EN ISO 374-5:2016. Their design and labelling corresponds to the requirements of the European Regulation 2017/745 on Medical Device 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 taking the gloves out from the packaging. 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. 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.
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. 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.
The chemical 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. It can be different if the chemical is used in a mixture. This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.
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 wrist injury caused by chemicals is considered to be minimal. Length suitable for tasks that require hand protection. Glove minimum length in accordance to EN 455-2 standard.

Components / hazardous components

Components used in making gloves may cause allergic reactions in some people. 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 consult a doctor.

Disposal

Used gloves should be treated as a contaminated material, therefore local regulations regarding the disposal of such materials should be applied.

Manufacturer

MERCATOR MEDICAL S.A.
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31-327 Cracow, Poland
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Permeation performance levels as per EN ISO 374-1:2016+A1:2018		
• 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+A1:2018		EN ISO 374-4:2019
Chemical	Level	Degradation [%]
40% Sodium Hydroxide (K)	6	-4.9
30% Hydrogen Peroxide (P)	3	12.6
37% Formaldehyde (T)	5	8.9

EN ISO 374-4: 2019 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

Test acc. to EN ISO 374-2:2019 – 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

EN ISO 374-5:2016 The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

Symbols used on the packaging

MD	Medical Device		Keep dry	VINYL	Vinyl gloves
PPE	Personal Protective Equipment		Keep away from sunlight		Powder-free gloves
	Manufacturer	30°C 10°C	Temperature limitation 10-30°C		For single use only
LOT	Lot / batch number	O_3	Keep away from ozone	NON STERILE	Non-sterile
REF	Catalogue number		Product quality is not ensured if the package is damaged	ISO 374-1/Type B XYZ	Designed to protect against to chemical risks acc. with EN ISO 374-1 (type B)
	Expiry date	21 PAP	Recyclable packaging	ISO 374-5:2016 VIRUS	Designed to protect against microorganisms risks acc. with EN ISO 374-5
	Date of manufacture		Package can be treated as municipal waste		Consult instructions for use
	Indicates compliance with the requirements of Ukrainian market		Suitable for food contact (for details check the instruction for use)		

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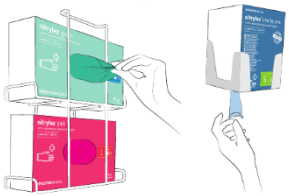
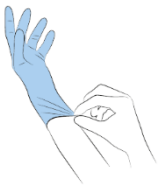
HOW TO PUT THE GLOVES ON?



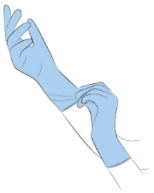
Take one glove from the box pulling by the cuff.

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.

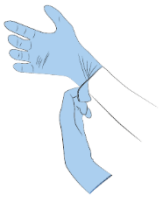
Take another glove from the box with the hand wearing a glove.



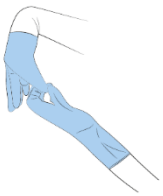
Put the glove on the hand and smooth it out.

Done!

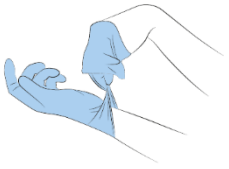
HOW TO TAKE THE GLOVES OFF?



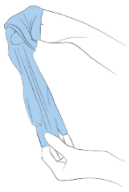
Hold the glove with a finger of the other hand at the cuff.



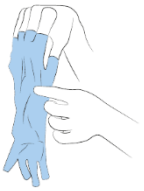
Slide the glove down to mid-palm.



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.