

## EU DECLARATION OF CONFORMITY

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

declares under its sole responsibility that following products:

Product Name:	Product Description:	Sizes	Reference Numbers:	
			EO	GAMMA
<b>COMFORT® POWDER-FREE</b>	Sterile (EO/GAMMA) Powder-Free Latex Surgical and Protective Gloves	6.0	RC10003060	RC10004060
		6.5	RC10003065	RC10004065
		7.0	RC10003070	RC10004070
		7.5	RC10003075	RC10004075
		8.0	RC10003080	RC10004080
		8.5	RC10003085	RC10004085
		9.0	RC10003090	RC10004090
<b>Classification:</b>	Class IIa rule 6 as per Annex IX of the Council Directive 93/42/EEC and Regulation of Minister of Health of 5 November 2010 on the way of classification of medical devices			
<b>UMDNS Code:</b>	11883			
<b>Notified Body:</b>	<b>DNV GL Presafe AS, No. 2460</b> Veritasveien 3 N-1363 Høvik, Norway			
<b>EC Certificate No.:</b>	11711-2017-CE-POL-NA-PS			

Conform to the applicable essential requirements of Annex I of the Medical Device Directive 93/42/EEC amended by the Directive 2007/47/EC. Conformity assessment procedure performed according to Annex II (excluding section 4) of the Medical Device Directive 93/42/EEC amended by the Directive 2007/47/EC. These products comply with European harmonized standards: EN ISO 13485:2016, EN ISO 14791:2012, EN ISO 15223-1:2016, EN 1041:2008, EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN 556-1:2001|AC:2006, EN ISO 11737-1:2006, EN ISO 11737-2:2009, EN ISO 11135-1:2007 (EO) or EN ISO 11137-1:2015 (Gamma), EN ISO 11137-2:2015 (Gamma), EN ISO 11138-2:2009 (EO), EN ISO 10993-1:2009|AC:2010, EN ISO 10993-5:2009, EN ISO 10993-7:2008 (EO), EN ISO 10993-10:2010.

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+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015, EN ISO 374-4:2019, 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. FI20/965656 issued by notified body:

**SGS FIMKO OY (0598)**

Takomotie 8, 00380, Helsinki, Finland

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

**SGS FIMKO OY (0598)**

Takomotie 8, 00380, Helsinki, Finland

Date and place of issue:

14.12.2020, Kraków

Signed on the behalf of the Manufacturer:



Wojciech Hercka

Product Documentation Manager

**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 - Śródmieście 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



# comfort<sup>®</sup> powder-free

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

## Short description of the product

Sterile, natural rubber latex surgical and protective gloves powder-free, for disposable use

## Full description of the product

Reference number	: RC10003060-90 RC10004060-90
Raw material	: natural rubber latex
Donning powder	: -
External surface	: textured, chlorinated
Internal surface	: chlorinated
Cuff	: beaded
Colour	: light yellow
Shape	: anatomic, hand specific
Size range	: 6.0; 6.5; 7.0; 7.5; 8.0; 8.5; 9.0
AQL	: 0.65
Sterilization	: Ethylene oxide (EO) / Gamma (R)
Packaging	: 1 pair per pouch, 50 pairs per dispenser, 400 pairs per carton
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.

It is recommended to protect the gloves against humidity. Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone.

## MDD classification & compliance

Gloves classified as medical device – class IIa under Council Directive 93/42/EEC.

Compliance with standards: EN ISO 13485:2016, EN ISO 14791:2012, EN ISO 15223-1:2016, EN 1041:2008, EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN 556-1:2001|AC:2006, EN ISO 11737-1:2006, EN ISO 11737-2:2009, EN ISO 11135-1:2007 (EO) or EN ISO 11137-1:2015 (Gamma), EN ISO 11137-2:2015 (Gamma), EN ISO 11138-2:2009 (EO), EN ISO 10993-1:2009|AC:2010, EN ISO 10993-5:2009, EN ISO 10993-7:2008 (EO), EN ISO 10993-10:2010.

DNV GL Presafe AS, Notified Body Number 2460:

**CE 2460**

MDD 93/42/EEC  
DNV GL Presafe AS  
Veritasveien 3  
N-1363 Høvik, Norway

## PPER classification & compliance

Gloves are category III Personal Protective Equipment as per Annex I of the Regulation 2016/425.

Compliance with standards: EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018 (type C), EN ISO 374-2:2019, EN 16523-1:2015, EN ISO 374-4:2019, EN ISO 374-5:2016.

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

**0598**

PPER 2016/425  
SGS FIMKO OY  
Takomotie 8  
00380 Helsinki, Finland

Declaration of Conformity can be found under below web address:

<https://en.mercatormedical.eu/>

## Intended use

Sterile, surgical and protective gloves, made from natural rubber latex, with thumb positioned towards the palm side of the index finger which reduces the fatigue on the hands, intended to be worn on the hands usually in surgical settings to provide barrier against potentially infectious fluids or other contaminants and to protect the patient by ensuring sterility of the wound environment. These gloves are intended for single use only. 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 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

Attention should be drawn to the fact that the confirmed protection level does not reflect the real working conditions where other factors may influence the protection level, for example, abrasion, degradation, atmospheric conditions. Users should take care when using the gloves. Using them solely according to their intended application. These are sterile gloves for single use only and are not intended for cleaning or re-sterilization. The protection is limited to the hand only, the results relate to the palm of gloves and there were tested under laboratory condition.

The gloves should be put on dry hands. Before usage, inspect the gloves for any defect or imperfections. 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 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.

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.

## 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. Natural rubber latex gloves may cause allergic reactions including anaphylactic reactions. 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

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[www.mercatormedical.eu](http://www.mercatormedical.eu)



## 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		EN ISO 374-4:2019 Degradation [%]	Test results acc. to EN 16523-1:2015		EN ISO 374-4:2019 Degradation [%]
Chemical	Level		Chemical	Level	
40 % Sodium hydroxide	Level 6	-30.8	37% Formaldehyde	Level 1	-24.4
30% Hydrogen peroxide	Level 6	12.1			
Test acc. to EN ISO 374-2:2019 – Level 3 (ISO 2859)			Test acc. EN ISO 374-5:2016		
Performance Level	AQL		Protection against bacteria & fungi	Pass	
Level 3	< 0.65		Protection against viruses	Pass	
Level 2	< 1.5				
Level 1	< 4.0				

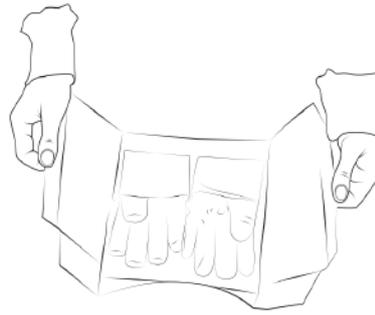
## Symbols which can be used on the packagings

	Do not re-use / gloves are intended for single use		Powdered gloves		Glove is fitting the right hand
	Sterilized with Ethylene oxide		Powder free gloves		Glove is fitting the left hand
	Sterilization with Gamma		Presence of polymer coating on the inner surface of the glove		the number of pairs of gloves in the envelope (1)
	Do not re-sterilize		Marking of gloves protecting against bacteria and fungi		the number of pairs of gloves in the dispenser (25)
	Raw material – natural rubber latex		Marking of gloves protecting against viruses, bacteria and fungi		the number of pairs of gloves in the dispenser (50)
	Raw material – neoprene		Marking of type A chemical resistant gloves. Six tested chemicals shall be identified by their code letter under pictogram		the number of pairs of gloves in the carton (100)
	Raw material - nitrile		Marking of type B chemical resistant gloves. Three tested chemicals shall be identified by their code letter under pictogram		the number of pairs of gloves in the carton (300)
	Lot / batch number		Marking of type C chemical resistant gloves		the number of pairs of gloves in the carton (400)
	Catalogue number		Keep away from moisture, store in a dry place		the number of sets of gloves in the dispenser (25)
	Manufacturer, symbol should be accompanied by name and address of Manufacturer		Keep away from solar and fluorescent light		the number of sets of gloves in the carton (200)
	EU Authorised Representative, symbol should be accompanied by name and address of Authorised Representative		Temperature limitation / gloves store in temperature 5-35°C		Consult instructions for use
	data produkcji		Keep away from ozone		Do not use, if package is damaged
	Expiry date		Package made from paper, qualify for recycling		Package is treated as municipal waste
	Indicates compliance with the requirements of Russian market		Indicates compliance with the requirements of Ukrainian market		

## Donning surgical gloves guideline



1) Open the packaging and remove the inner sachet containing the gloves.



2) Holding it by the wings, open the sachet.



3) Holding the exposed inside cuff of the left glove with the right hand, put on the glove.



4) Insert the left, gloved hand into the cuff opening of the right glove.



5) Pull the glove onto the right hand.



6) Pull the gloves up over the cuffs of the gown.