



**EU Declaration of Conformity  
according to MDR**

**Document ID:** PD-705856 Rev:2  
**Created by:** Pam Hague  
**State:** Released  
**Approved by:** Karin Darle Olsson  
**Release date:** 2022-06-22 11:32:21

**Title:** MDR DoC Biogel PC Sterile Surgical Gloves

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden, SRN SE-MF-000014042, being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of the Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product name:	Biogel PC Sterile Surgical Gloves
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Product Classification: MDR Class IIa  
MDR Classification Rule: 6, 7  
Sterility: Sterile  
Measuring Function: No

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IX
Common Specification: No CS is applicable

Certificate number:	MDR 722028	
Issued by:	BSi	Id No: 2797
	(Notified Body Name)	
<i>NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.</i>		

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: 2022-06-22      Function: Regulatory Affairs Excellence Manager

Name: Karin Darle Olsson

Signature:



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<b>Generic product information</b>	
<b>Intended Purpose:</b>	Intended for single-use to cover the hands and wrists for short term and transient invasive use both surgically and with respect to body orifices. Acts as a barrier to cross-infection, thereby preventing diseases. A powder-free sterile glove is a disposable device made of synthetic or natural rubber latex that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.
<b>Basic UDI-DI:</b>	733243000000000072JZ
<b>GMDN Code:</b>	57970 Polychloroprene surgical glove, non-powdered

<b>Product References Covered by this Declaration:</b>	<b>Product Descriptor:</b>
28855	Biogel Skinsense Indicator 5.5 x 2x25
28860	Biogel Skinsense Indicator 6.0 x 2x25
28865	Biogel Skinsense Indicator 6.5 x 2x25
28870	Biogel Skinsense Indicator 7.0 x 2x25
28875	Biogel Skinsense Indicator 7.5 x 2x25
28880	Biogel Skinsense Indicator 8.0 x 2x25
28885	Biogel Skinsense Indicator 8.5 x 2x25
31455	Biogel Skinsense 5.5x50
31460	Biogel Skinsense 6.0x50
31465	Biogel Skinsense 6.5x50
31470	Biogel Skinsense 7.0x50
31475	Biogel Skinsense 7.5x50
31480	Biogel Skinsense 8.0x50
31485	Biogel Skinsense 8.5x50
31490	Biogel Skinsense 9.0 x 40
40655	Biogel Skinsense Underglove 5.5x50
40660	Biogel Skinsense Underglove 6.0x50
40665	Biogel Skinsense Underglove 6.5x50



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40670	Biogel Skinsense Underglove 7.0x50
40675	Biogel Skinsense Underglove 7.5x50
40680	Biogel Skinsense Underglove 8.0x50
40685	Biogel Skinsense Underglove 8.5x50
40690	Biogel Skinsense Underglove 9.0x40
42955	Biogel NeoDerm 5.5x50
42960	Biogel NeoDerm 6.0x50
42965	Biogel NeoDerm 6.5x50
42970	Biogel NeoDerm 7.0x50
42975	Biogel NeoDerm 7.5x50
42980	Biogel NeoDerm 8.0x50
42985	Biogel NeoDerm 8.5x50
42990	Biogel NeoDerm 9.0x40
50955	Biogel Skinsense 5.5x50
50960	Biogel Skinsense 6.0x50
50965	Biogel Skinsense 6.5x50
50970	Biogel Skinsense 7.0x50
50975	Biogel Skinsense 7.5x50
50980	Biogel Skinsense 8.0x50
50985	Biogel Skinsense 8.5x50
50990	Biogel Skinsense 9.0x40