



**EU Declaration of Conformity
according to MDR**

Document ID: PD-705862 Rev:2
Created by: Pam Hague
State: Released
Approved by: Karin Darle Olsson
Release date: 2022-06-22 11:32:22

Title: MDR DoC Biogel PI 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 PI 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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Generic product information	
Intended Purpose:	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.
Basic UDI-DI:	733243000000000072JZ
GMDN Code:	56293 Polyisoprene surgical glove, non-powdered

Product References Covered by this Declaration:	Product Descriptor:
40855	Biogel Skinsense PI 5.5 x50
40860	Biogel Skinsense PI 6.0 x50
40865	Biogel Skinsense PI 6.5 x50
40870	Biogel Skinsense PI 7.0 x50
40875	Biogel Skinsense PI 7.5 x50
40880	Biogel Skinsense PI 8.0 x50
40885	Biogel Skinsense PI 8.5 x50
40890	Biogel Skinsense PI 9.0 x40
40955	Biogel PI UltraTouch 5.5x50
40960	Biogel PI UltraTouch 6.0x50
40965	Biogel PI UltraTouch 6.5x50
40970	Biogel PI UltraTouch 7.0x50
40975	Biogel PI UltraTouch 7.5x50
40980	Biogel PI UltraTouch 8.0x50
40985	Biogel PI UltraTouch 8.5x50
40990	Biogel PI UltraTouch 9.0x40
41155	Biogel PI UltraTouch 5.5 x50
41160	Biogel PI UltraTouch 6.0 x50



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41165	Biogel PI UltraTouch 6.5 x50
41170	Biogel PI UltraTouch 7.0 x50
41175	Biogel PI UltraTouch 7.5 x50
41180	Biogel PI UltraTouch 8.0 x50
41185	Biogel PI UltraTouch 8.5 x50
41190	Biogel PI UltraTouch 9.0 x40
41455	Biogel PI Indicator System 5.5 2 x 25
41460	Biogel PI Indicator System 6.0 2 x 25
41465	Biogel PI Indicator System 6.5 2 x 25
41470	Biogel PI Indicator System 7.0 2 x 25
41475	Biogel PI Indicator System 7.5 2 x 25
41480	Biogel PI Indicator System 8.0 2 x 25
41485	Biogel PI Indicator System 8.5 2 x 25
41655	Biogel PI Indicator Underglove 5.5 x 50
41660	Biogel PI Indicator Underglove 6.0 x 50
41665	Biogel PI Indicator Underglove 6.5 x 50
41670	Biogel PI Indicator Underglove 7.0 x 50
41675	Biogel PI Indicator Underglove 7.5 x 50
41680	Biogel PI Indicator Underglove 8.0 x 50
41685	Biogel PI Indicator Underglove 8.5 x 50
41690	Biogel PI Indicator Underglove 9.0 x 40
42155	Biogel PI UltraTouch G 5.5x50
42160	Biogel PI UltraTouch G 6.0x50
42165	Biogel PI UltraTouch G 6.5x50
42170	Biogel PI UltraTouch G 7.0x50
42175	Biogel PI UltraTouch G 7.5x50
42180	Biogel PI UltraTouch G 8.0x50



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42185	Biogel PI UltraTouch G 8.5x50
42190	Biogel PI UltraTouch G 9.0x40
42655	Biogel PI UltraTouch M 5.5x50
42660	Biogel PI UltraTouch M 6.0x50
42665	Biogel PI UltraTouch M 6.5x50
42670	Biogel PI UltraTouch M 7.0x50
42675	Biogel PI UltraTouch M 7.5x50
42680	Biogel PI UltraTouch M 8.0x50
42685	Biogel PI UltraTouch M 8.5x50
42690	Biogel PI UltraTouch M 9.0x40
43155	Biogel PI UltraTouch 5.5x50
43160	Biogel PI UltraTouch 6.0x50
43165	Biogel PI UltraTouch 6.5x50
43170	Biogel PI UltraTouch 7.0x50
43175	Biogel PI UltraTouch 7.5x50
43180	Biogel PI UltraTouch 8.0x50
43185	Biogel PI UltraTouch 8.5x50
43190	Biogel PI UltraTouch 9.0x40
45355	Biogel PI UltraTouch S Indicator System 5.5x50
45360	Biogel PI UltraTouch S Indicator System 6.0x50
45365	Biogel PI UltraTouch S Indicator System 6.5x50
45370	Biogel PI UltraTouch S Indicator System 7.0x50
45375	Biogel PI UltraTouch S Indicator System 7.5x50
45380	Biogel PI UltraTouch S Indicator System 8.0x50
45385	Biogel PI UltraTouch S Indicator System 8.5x50
45555	Biogel PI UltraTouch S 5.5x50



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45560	Biogel PI UltraTouch S 6.0x50
45565	Biogel PI UltraTouch S 6.5x50
45570	Biogel PI UltraTouch S 7.0x50
45575	Biogel PI UltraTouch S 7.5x50
45580	Biogel PI UltraTouch S 8.0x50
45585	Biogel PI UltraTouch S 8.5x50
45590	Biogel PI UltraTouch S 9.0x40
45955	Biogel PI UltraTouch S Indicator Underglove 5.5x50
45960	Biogel PI UltraTouch S Indicator Underglove 6.0x50
45965	Biogel PI UltraTouch S Indicator Underglove 6.5x50
45970	Biogel PI UltraTouch S Indicator Underglove 7.0x50
45975	Biogel PI UltraTouch S Indicator Underglove 7.5x50
45980	Biogel PI UltraTouch S Indicator Underglove 8.0x50
45985	Biogel PI UltraTouch S Indicator Underglove 8.5x50
45990	Biogel PI UltraTouch S Indicator Underglove 9.0x40
47660	Biogel PI OrthoPro 6.0x40
47665	Biogel PI OrthoPro 6.5x40
47670	Biogel PI OrthoPro 7.0x40
47675	Biogel PI OrthoPro 7.5x40
47680	Biogel PI OrthoPro 8.0x40
47685	Biogel PI OrthoPro 8.5x40
47690	Biogel PI OrthoPro 9.0x40
47960	Biogel PI Pro-Fit 6.0x50
47965	Biogel PI Pro-Fit 6.5x50
47970	Biogel PI Pro-Fit 7.0x50
47975	Biogel PI Pro-Fit 7.5x50



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47980	Biogel PI Pro-Fit 8.0x50
47985	Biogel PI Pro-Fit 8.5x50
47990	Biogel PI Pro-Fit 9.0x40
48355	Biogel PI Micro Indicator System 5.5x50
48360	Biogel PI Micro Indicator System 6.0x50
48365	Biogel PI Micro Indicator System 6.5x50
48370	Biogel PI Micro Indicator System 7.0x50
48375	Biogel PI Micro Indicator System 7.5x50
48380	Biogel PI Micro Indicator System 8.0x50
48385	Biogel PI Micro Indicator System 8.5x50
48555	Biogel PI Micro 5.5x50
48560	Biogel PI Micro 6.0x50
48565	Biogel PI Micro 6.5x50
48570	Biogel PI Micro 7.0x50
48575	Biogel PI Micro 7.5x50
48580	Biogel PI Micro 8.0x50
48585	Biogel PI Micro 8.5x50
48590	Biogel PI Micro 9.0x50
48955	Biogel PI Micro Indicator Underglove 5.5x50
48960	Biogel PI Micro Indicator Underglove 6.0x50
48965	Biogel PI Micro Indicator Underglove 6.5x50
48970	Biogel PI Micro Indicator Underglove 7.0x50
48975	Biogel PI Micro Indicator Underglove 7.5x50
48980	Biogel PI Micro Indicator Underglove 8.0x50
48985	Biogel PI Micro Indicator Underglove 8.5x50
48990	Biogel PI Micro Indicator Underglove 9.0x40