



EU Declaration of Conformity according to MDR

Document ID: PD-705742 **Rev:**3
Created by: Pam Hague
State: Released
Approved by: Karin Darle Olsson
Release date: 2022-06-22 11:32:21

Title: MDR DoC Biogel NRL Sterile Surgeons 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 NRL 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)

NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

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:	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:	733243000000000071JX
GMDN Code:	47178 Hevea-latex surgical glove, non-powdered

Product References Covered by this Declaration:	Product Descriptor:
30455	Biogel Surgeons 5.5 x 50 US
30460	Biogel Surgeons 6.0 x 50 US
30465	Biogel Surgeons 6.5 x 50 US
30470	Biogel Surgeons 7.0 x 50 US
30475	Biogel Surgeons 7.5 x 50 US
30480	Biogel Surgeons 8.0 x 50 US
30485	Biogel Surgeons 8.5 x 50 US
30490	Biogel Surgeons 9.0 x 40 US
30555	Biogel Micro Surgeons 5.5x50US
30560	Biogel Micro Surgeons 6.0x50US
30565	Biogel Micro Surgeons 6.5x50US
30570	Biogel Micro Surgeons 7.0x50US
30575	Biogel Micro Surgeons 7.5x50US
30580	Biogel Micro Surgeons 8.0x50US
30585	Biogel Micro Surgeons 8.5x50US
30590	Biogel Micro Surgeons 9.0x40US
30655	Biogel Sensor 5.5 x 50 US
30660	Biogel Sensor 6.0 x 50 US
30665	Biogel Sensor 6.5 x 50 US



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30670	Biogel Sensor 7.0 x 50 US
30675	Biogel Sensor 7.5 x 50 US
30680	Biogel Sensor 8.0 x 50 US
30685	Biogel Sensor 8.5 x 50 US
30690	Biogel Sensor 9.0 x 40 US
31060	Biogel Opti Orthopaedic 6.0x40US
31065	Biogel Opti Orthopaedic 6.5x40US
31070	Biogel Opti Orthopaedic 7.0x40US
31075	Biogel Opti Orthopaedic 7.5x40US
31080	Biogel Opti Orthopaedic 8.0x40US
31085	Biogel Opti Orthopaedic 8.5x40US
31090	Biogel Opti Orthopaedic 9.0x40US
31255	Biogel Indicator Uglove 5.5x50
31260	Biogel Indicator Uglove 6.0x50
31265	Biogel Indicator Uglove 6.5x50
31270	Biogel Indicator Uglove 7.0x50
31275	Biogel Indicator Uglove 7.5x50
31280	Biogel Indicator Uglove 8.0x50
31285	Biogel Indicator Uglove 8.5x50
31290	Biogel Indicator U/glove9.0x40
60755	Biogel Eclipse Indic 5.5x2x25EUR
60760	Biogel Eclipse Indic 6.0x2x25EUR
60765	Biogel Eclipse Indic 6.5x2x25EUR
60770	Biogel Eclipse Indic 7.0x2x25EUR
60775	Biogel Eclipse Indic 7.5x2x25EUR
60780	Biogel Eclipse Indic 8.0x2x25EUR
60785	Biogel Eclipse Indic 8.5x2x25EUR



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60855	Biogel Eclipse Reveal 5.5x2x25UK
60860	Biogel Eclipse Reveal 6.0x2x25UK
60865	Biogel Eclipse Reveal 6.5x2x25UK
60870	Biogel Eclipse Reveal 7.0x2x25UK
60875	Biogel Eclipse Reveal 7.5x2x25UK
60880	Biogel Eclipse Reveal 8.0x2x25UK
60885	Biogel Eclipse Reveal 8.5x2x25UK
60955	Eclipse Ind Uglove 5.5 x50 UK
60960	Eclipse Ind Uglove 6.0 x50 UK
60965	Eclipse Ind Uglove 6.5 x50 UK
60970	Eclipse Ind Uglove 7.0 x50 UK
60975	Eclipse Ind Uglove 7.5 x50 UK
60980	Eclipse Ind Uglove 8.0 x50 UK
60985	Eclipse Ind Uglove 8.5 x50 UK
60990	Eclipse Ind Uglove 9.0 x50 UK
73255	Eclipse Ind Uglove 5.5 x50 EUR
73260	Eclipse Ind Uglove 6.0 x50 EUR
73265	Eclipse Ind Uglove 6.5 x50 EUR
73270	Eclipse Ind Uglove 7.0 x50 EUR
73275	Eclipse Ind Uglove 7.5 x50 EUR
73280	Eclipse Ind Uglove 8.0 x50 EUR
73285	Eclipse Ind Uglove 8.5 x50 EUR
73290	Eclipse Ind Uglove 9.0 x40 EUR
75055	Biogel Eclipse 5.5 x50 UK
75060	Biogel Eclipse 6.0 x50 UK
75065	Biogel Eclipse 6.5 x50 UK
75070	Biogel Eclipse 7.0 x50 UK



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75075	Biogel Eclipse 7.5 x50 UK
75080	Biogel Eclipse 8.0 x50 UK
75085	Biogel Eclipse 8.5 x50 UK
75090	Biogel Eclipse 9.0 x40 UK
75155	Biogel Eclipse 5.5 x50 EUR
75160	Biogel Eclipse 6.0 x50 EUR
75165	Biogel Eclipse 6.5 x50 EUR
75170	Biogel Eclipse 7.0 x50 EUR
75175	Biogel Eclipse 7.5 x50 EUR
75180	Biogel Eclipse 8.0 x50 EUR
75185	Biogel Eclipse 8.5 x50 EUR
75190	Biogel Eclipse 9.0 x40 EUR
75255	Biogel Eclipse 5.5 x50 US
75260	Biogel Eclipse 6.0 x50 US
75265	Biogel Eclipse 6.5 x50 US
75270	Biogel Eclipse 7.0 x50 US
75275	Biogel Eclipse 7.5 x50 US
75280	Biogel Eclipse 8.0 x50 US
75285	Biogel Eclipse 8.5 x50 US
75290	Biogel Eclipse 9.0 x40 US
82255	Biogel Surgeons 5.5 x50 EUR
82260	Biogel Surgeons 6.0 x50 EUR
82265	Biogel Surgeons 6.5 x50 EUR
82270	Biogel Surgeons 7.0 x50 EUR
82275	Biogel Surgeons 7.5 x50 EUR
82280	Biogel Surgeons 8.0 x50 EUR
82285	Biogel Surgeons 8.5 x50 EUR



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82290	Biogel Surgeons 9.0 x40 EUR
82355	Biogel MicroSurgeons 5.5x50EUR
82360	Biogel MicroSurgeons 6.0x50EUR
82365	Biogel MicroSurgeons 6.5x50EUR
82370	Biogel MicroSurgeons 7.0x50EUR
82375	Biogel MicroSurgeons 7.5x50EUR
82380	Biogel MicroSurgeons 8.0x50EUR
82385	Biogel MicroSurgeons 8.5x50EUR
82390	Biogel MicroSurgeons 9.0x40EUR
82555	Biogel Super Sens 5.5 x50 EUR
82560	Biogel Super Sens 6.0 x50 EUR
82565	Biogel Super Sens 6.5 x50 EUR
82570	Biogel Super Sens 7.0 x50 EUR
82575	Biogel Super Sens 7.5 x50 EUR
82580	Biogel Super Sens 8.0 x50 EUR
82585	Biogel Super Sens 8.5 x50 EUR
82590	Biogel Super Sens 9.0 x40 EUR
84255	Biogel IndicatorDD 5.5 2x25EUR
84260	Biogel IndicatorDD 6.0 2x25EUR
84265	Biogel IndicatorDD 6.5 2x25EUR
84270	Biogel IndicatorDD 7.0 2x25EUR
84275	Biogel IndicatorDD 7.5 2x25EUR
84280	Biogel IndicatorDD 8.0 2x25EUR
84285	Biogel IndicatorDD 8.5 2x25EUR
96155	Biogel Surgeons 5.5 x50 UK
96160	Biogel Surgeons 6.0 x50 UK
96165	Biogel Surgeons 6.5 x50 UK



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96170	Biogel Surgeons 7.0 x50 UK
96175	Biogel Surgeons 7.5 x50 UK
96180	Biogel Surgeons 8.0 x50 UK
96185	Biogel Surgeons 8.5 x50 UK
96190	Biogel Surgeons 9.0 x40 UK
96255	Biogel Micro Surgeons 5.5x50UK
96260	Biogel Micro Surgeons 6.0x50UK
96265	Biogel Micro Surgeons 6.5x50UK
96270	Biogel Micro Surgeons 7.0x50UK
96275	Biogel Micro Surgeons 7.5x50UK
96280	Biogel Micro Surgeons 8.0x50UK
96285	Biogel Micro Surgeons 8.5x50UK
96290	Biogel Micro Surgeons 9.0x40UK
97555	Biogel Super Sens 5.5 x 50 UK
97560	Biogel Super Sens 6.0 x 50 UK
97565	Biogel Super Sens 6.5 x 50 UK
97570	Biogel Super Sens 7.0 x 50 UK
97575	Biogel Super Sens 7.5 x 50 UK
97580	Biogel Super Sens 8.0 x 50 UK
97585	Biogel Super Sens 8.5 x 50 UK
97590	Biogel Super Sens 9.0 x 40 UK
9931255	Biogel Indicator Uglove 5.5x50
9931260	Biogel Indicator Uglove 6.0x50
9931265	Biogel Indicator Uglove 6.5x50
9931270	Biogel Indicator Uglove 7.0x50
9931275	Biogel Indicator Uglove 7.5x50
9931280	Biogel Indicator Uglove 8.0x50



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9931285	Biogel Indicator Uglove 8.5x50
9931290	Biogel Indicator Uglove 9.0x40