

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden 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 Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/ Product name:	Biogel sterile DPNRL surgical gloves
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Product classification: **IIa**Sterility Status: **Sterile**Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
Annex/es:	II

Certificate number:	CE 01965
Issued by:	BSI (2797)
For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2019-10-21**Function: **Regulatory Affairs Manager
(Antiseptics)**Name: **Victoria Stead**

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
60755	Biogel Eclipse Indic 5.5x2x25EUR	47178 Hevea-latex surgical glove, non-powdered
60760	Biogel Eclipse Indic 6.0x2x25EUR	47178 Hevea-latex surgical glove, non-powdered
60765	Biogel Eclipse Indic 6.5x2x25EUR	47178 Hevea-latex surgical glove, non-powdered
60770	Biogel Eclipse Indic 7.0x2x25EUR	47178 Hevea-latex surgical glove, non-powdered
60775	Biogel Eclipse Indic 7.5x2x25EUR	47178 Hevea-latex surgical glove, non-powdered
60780	Biogel Eclipse Indic 8.0x2x25EUR	47178 Hevea-latex surgical glove, non-powdered
60785	Biogel Eclipse Indic 8.5x2x25EUR	47178 Hevea-latex surgical glove, non-powdered
60855	Biogel Eclipse Reveal 5.5x2x25UK	47178 Hevea-latex surgical glove, non-powdered
60860	Biogel Eclipse Reveal 6.0x2x25UK	47178 Hevea-latex surgical glove, non-powdered
60865	Biogel Eclipse Reveal 6.5x2x25UK	47178 Hevea-latex surgical glove, non-powdered

Product Reference:	Product Descriptor:	GMDN Code:
60870	Biogel Eclipse Reveal 7.0x2x25UK	47178 Hevea-latex surgical glove, non-powdered
60875	Biogel Eclipse Reveal 7.5x2x25UK	47178 Hevea-latex surgical glove, non-powdered
60880	Biogel Eclipse Reveal 8.0x2x25UK	47178 Hevea-latex surgical glove, non-powdered
60885	Biogel Eclipse Reveal 8.5x2x25UK	47178 Hevea-latex surgical glove, non-powdered
60955	Eclipse Ind Uglove 5.5 x50 UK	47178 Hevea-latex surgical glove, non-powdered
60960	Eclipse Ind Uglove 6.0 x50 UK	47178 Hevea-latex surgical glove, non-powdered
60965	Eclipse Ind Uglove 6.5 x50 UK	47178 Hevea-latex surgical glove, non-powdered
60970	Eclipse Ind Uglove 7.0 x50 UK	47178 Hevea-latex surgical glove, non-powdered
60975	Eclipse Ind Uglove 7.5 x50 UK	47178 Hevea-latex surgical glove, non-powdered
60980	Eclipse Ind Uglove 8.0 x50 UK	47178 Hevea-latex surgical glove, non-powdered
60985	Eclipse Ind Uglove 8.5 x50 UK	47178 Hevea-latex surgical glove, non-powdered

Product Reference:	Product Descriptor:	GMDN Code:
60990	Eclipse Ind Uglove 9.0 x50 UK	47178 Hevea-latex surgical glove, non-powdered
73255	Eclipse Ind Uglove 5.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
73260	Eclipse Ind Uglove 6.0 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
73265	Eclipse Ind Uglove 6.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
73270	Eclipse Ind Uglove 7.0 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
73275	Eclipse Ind Uglove 7.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
73280	Eclipse Ind Uglove 8.0 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
73285	Eclipse Ind Uglove 8.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
73290	Eclipse Ind Uglove 9.0 x40 EUR	47178 Hevea-latex surgical glove, non-powdered
75055	Biogel Eclipse 5.5 x50 UK	47178 Hevea-latex surgical glove, non-powdered
75060	Biogel Eclipse 6.0 x50 UK	47178 Hevea-latex surgical glove, non-powdered

Product Reference:	Product Descriptor:	GMDN Code:
75065	Biogel Eclipse 6.5 x50 UK	47178 Hevea-latex surgical glove, non-powdered
75070	Biogel Eclipse 7.0 x50 UK	47178 Hevea-latex surgical glove, non-powdered
75075	Biogel Eclipse 7.5 x50 UK	47178 Hevea-latex surgical glove, non-powdered
75080	Biogel Eclipse 8.0 x50 UK	47178 Hevea-latex surgical glove, non-powdered
75085	Biogel Eclipse 8.5 x50 UK	47178 Hevea-latex surgical glove, non-powdered
75090	Biogel Eclipse 9.0 x40 UK	47178 Hevea-latex surgical glove, non-powdered
75155	Biogel Eclipse 5.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
75160	Biogel Eclipse 6.0 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
75165	Biogel Eclipse 6.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
75170	Biogel Eclipse 7.0 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
75175	Biogel Eclipse 7.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered

Product Reference:	Product Descriptor:	GMDN Code:
75180	Biogel Eclipse 8.0 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
75185	Biogel Eclipse 8.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
75190	Biogel Eclipse 9.0 x40 EUR	47178 Hevea-latex surgical glove, non-powdered
75255	Biogel Eclipse 5.5 x50 US	47178 Hevea-latex surgical glove, non-powdered
75260	Biogel Eclipse 6.0 x50 US	47178 Hevea-latex surgical glove, non-powdered
75265	Biogel Eclipse 6.5 x50 US	47178 Hevea-latex surgical glove, non-powdered
75270	Biogel Eclipse 7.0 x50 US	47178 Hevea-latex surgical glove, non-powdered
75275	Biogel Eclipse 7.5 x50 US	47178 Hevea-latex surgical glove, non-powdered
75280	Biogel Eclipse 8.0 x50 US	47178 Hevea-latex surgical glove, non-powdered
75285	Biogel Eclipse 8.5 x50 US	47178 Hevea-latex surgical glove, non-powdered
75290	Biogel Eclipse 9.0 x40 US	47178 Hevea-latex surgical glove, non-powdered