



**EU Declaration of Conformity  
according to MDR**

**Document ID:** PD-573435 Rev:02  
**Created by:** Pam Hague  
**State:** Released  
**Approved by:** Karin Darle Olsson  
**Release date:** 2022-06-22 11:32:21

**Title:** NRL sterile exam glove

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:	NRL sterile exam glove
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Product Classification: MDR Class IS  
MDR Classification Rule: 5  
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 invasive use with respect to body orifices only. They act as a barrier to cross-infection, thereby preventing diseases. A powder-free, sterile glove which is made of natural rubber latex and are disposable devices that are intended to be worn on the hands, usually in dental/diagnostic settings worn by healthcare professionals in a clinical setting, to provide a barrier against potentially infectious materials and other contaminants.
<b>Basic UDI-DI:</b>	733243000000000070JV
<b>GMDN Code:</b>	47172 Hevea-latex examination/treatment glove, non-powdered, non-antimicrobial

<b>Product References Covered by this Declaration:</b>	<b>Product Descriptor:</b>
9999055	Biogel Dental Sterile 5.5 x 10
9999060	Biogel Dental Sterile 6.0 x 10
9999065	Biogel Dental Sterile 6.5 x10
9999070	Biogel Dental Sterile 7.0 x10
9999075	Biogel Dental Sterile 7.5 x 10
9999080	Biogel Dental Sterile 8.0 x 10
9999085	Biogel Dental Sterile 8.5 x 10
9999090	Biogel Dental Sterile 9.0 x 10