

Title: NRL sterile exam glove

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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 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: **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 (2797)

NB. 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: **2020-07-10** **Function:** **Regulatory Affairs Director**

Name: **Christina Lewing**

Signature:



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Intended Purpose: 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 reducing the risk of infection. A powder-free sterile exam glove is a disposable device that is intended to be worn on the hands, usually in dental/diagnostic settings, to provide a barrier against potentially infectious materials and other contaminants.

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
9999055	Biogel Dental Sterile 5.5 x 10	733243000000000070JV	59096 Hevea-latex examination / treatment glove, non-powdered, sterile
9999060	Biogel Dental Sterile 6.0 x 10	733243000000000070JV	59096 Hevea-latex examination / treatment glove, non-powdered, sterile
9999065	Biogel Dental Sterile 6.5 x10	733243000000000070JV	59096 Hevea-latex examination / treatment glove, non-powdered, sterile
9999070	Biogel Dental Sterile 7.0 x10	733243000000000070JV	59096 Hevea-latex examination / treatment glove, non-powdered, sterile
9999075	Biogel Dental Sterile 7.5 x 10	733243000000000070JV	59096 Hevea-latex examination / treatment glove, non-powdered, sterile
9999080	Biogel Dental Sterile 8.0 x 10	733243000000000070JV	59096 Hevea-latex examination / treatment glove, non-powdered, sterile



**EU Declaration of Conformity
according to MDR**

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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
9999085	Biogel Dental Sterile 8.5 x 10	733243000000000070JV	59096 Hevea-latex examination / treatment glove, non-powdered, sterile
9999090	Biogel Dental Sterile 9.0 x 10	733243000000000070JV	59096 Hevea-latex examination / treatment glove, non-powdered, sterile

Revision history	
Revision	Comment
01	revised to change document owner