



**EU Declaration of Conformity  
according to MDR**

Document ID: **PD-573434 Rev: 01**  
Created by: Pam Hague  
Approved by: Christina Lewing  
Approval date: 2020-07-10

**Title:** NRL non-sterile exam gloves

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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:	<b>NRL non-sterile exam gloves</b>
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Product classification: **I**  
MDR Classification Rule: **5**  
Sterility: **Non-sterile**  
Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
Annex/es:	<b>IV</b>
Common Specification:	<b>No CS is applicable</b>

Certificate number:	<b>Not Applicable</b>
Issued by:	<b>Not Applicable</b>
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 transient and 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 non 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:**

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>Basic UDI-DI:</b>	<b>GMDN Code:</b>
30260	Biogel Dental 6.0 x25 Japan	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
30265	Biogel Dental 6.5 x25 Japan	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
30270	Biogel Dental 7.0 x25 Japan	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
30275	Biogel Dental 7.5 x25 Japan	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
30280	Biogel Dental 8.0 x25 Japan	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
30285	Biogel Dental 8.5 x25 Japan	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile



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<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>Basic UDI-DI:</b>	<b>GMDN Code:</b>
30290	Biogel Dental 9.0 x25 Japan	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
30355	Biogel Diagnostic 5.5 x25 US	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
30360	Biogel Diagnostic 6.0 x25 US	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
30365	Biogel Diagnostic 6.5 x25 US	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
30370	Biogel Diagnostic 7.0 x25 US	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
30375	Biogel Diagnostic 7.5 x25 US	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
30380	Biogel Diagnostic 8.0 x25 US	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
30385	Biogel Diagnostic 8.5 x25 US	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
30390	Biogel Diagnostic 9.0 x25 US	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile



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<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>Basic UDI-DI:</b>	<b>GMDN Code:</b>
5636	Biogel Dental 5.5 x25 UK EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
5637	Biogel Dental 6.0 x25 UK EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
5638	Biogel Dental 6.5 x25 UK EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
5639	Biogel Dental 7.0 x25 UK EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
5640	Biogel Dental 7.5 x25 UK EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
5641	Biogel Dental 8.0 x25 UK EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
5642	Biogel Dental 8.5 x25 UK EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
5643	Biogel Dental 9.0 x25 UK EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile
5653	Biogel Diagnostic 5.5 x25 EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non- sterile



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
5654	Biogel Diagnostic 6.0 x25 EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non-sterile
5655	Biogel Diagnostic 6.5 x25 EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non-sterile
5656	Biogel Diagnostic 7.0 x25 EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non-sterile
5657	Biogel Diagnostic 7.5 x25 EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non-sterile
5658	Biogel Diagnostic 8.0 x25 EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non-sterile
5659	Biogel Diagnostic 8.5 x25 EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non-sterile
5660	Biogel Diagnostic 9.0 x25 EUR	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non-sterile
9930255	Biogel Dental 5.5 x25 Japan	73324300000000068KA	47172 Hevea-latex examination / treatment glove, non-powdered, non-sterile

Revision history	
Revision	Comment



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01	revised to add missing code 9930255
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