

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:	<b>Biogel Sterile latex powder free surgical gloves</b>
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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:	<b>II</b>

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: **2019-10-22**Function: **Regulatory Affairs Manager  
(Antiseptics)**Name: **Victoria Stead**

Signature:



**Product(s) covered by this declaration:**

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
30455	Biogel Surgeons 5.5 x 50 US	47178 Hevea-latex surgical glove, non-powdered
30460	Biogel Surgeons 6.0 x 50 US	47178 Hevea-latex surgical glove, non-powdered
30465	Biogel Surgeons 6.5 x 50 US	47178 Hevea-latex surgical glove, non-powdered
30470	Biogel Surgeons 7.0 x 50 US	47178 Hevea-latex surgical glove, non-powdered
30475	Biogel Surgeons 7.5 x 50 US	47178 Hevea-latex surgical glove, non-powdered
30480	Biogel Surgeons 8.0 x 50 US	47178 Hevea-latex surgical glove, non-powdered
30485	Biogel Surgeons 8.5 x 50 US	47178 Hevea-latex surgical glove, non-powdered
30490	Biogel Surgeons 9.0 x 40 US	47178 Hevea-latex surgical glove, non-powdered
30555	Biogel Micro Surgeons 5.5x50US	47178 Hevea-latex surgical glove, non-powdered
30560	Biogel Micro Surgeons 6.0x50US	47178 Hevea-latex surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
30565	Biogel Micro Surgeons 6.5x50US	47178 Hevea-latex surgical glove, non-powdered
30570	Biogel Micro Surgeons 7.0x50US	47178 Hevea-latex surgical glove, non-powdered
30575	Biogel Micro Surgeons 7.5x50US	47178 Hevea-latex surgical glove, non-powdered
30580	Biogel Micro Surgeons 8.0x50US	47178 Hevea-latex surgical glove, non-powdered
30585	Biogel Micro Surgeons 8.5x50US	47178 Hevea-latex surgical glove, non-powdered
30590	Biogel Micro Surgeons 9.0x40US	47178 Hevea-latex surgical glove, non-powdered
30655	Biogel Sensor 5.5 x 50 US	47178 Hevea-latex surgical glove, non-powdered
30660	Biogel Sensor 6.0 x 50 US	47178 Hevea-latex surgical glove, non-powdered
30665	Biogel Sensor 6.5 x 50 US	47178 Hevea-latex surgical glove, non-powdered
30670	Biogel Sensor 7.0 x 50 US	47178 Hevea-latex surgical glove, non-powdered
30675	Biogel Sensor 7.5 x 50 US	47178 Hevea-latex surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
30680	Biogel Sensor 8.0 x 50 US	47178 Hevea-latex surgical glove, non-powdered
30685	Biogel Sensor 8.5 x 50 US	47178 Hevea-latex surgical glove, non-powdered
30690	Biogel Sensor 9.0 x 40 US	47178 Hevea-latex surgical glove, non-powdered
31060	Biogel Opti Orthopaedic 6.0x40US	47178 Hevea-latex surgical glove, non-powdered
31065	Biogel Opti Orthopaedic 6.5x40US	47178 Hevea-latex surgical glove, non-powdered
31070	Biogel Opti Orthopaedic 7.0x40US	47178 Hevea-latex surgical glove, non-powdered
31075	Biogel Opti Orthopaedic 7.5x40US	47178 Hevea-latex surgical glove, non-powdered
31080	Biogel Opti Orthopaedic 8.0x40US	47178 Hevea-latex surgical glove, non-powdered
31085	Biogel Opti Orthopaedic 8.5x40US	47178 Hevea-latex surgical glove, non-powdered
31090	Biogel Opti Orthopaedic 9.0x40US	47178 Hevea-latex surgical glove, non-powdered
31255	Biogel Indicator Uglove 5.5x50	47178 Hevea-latex surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
31260	Biogel Indicator Uglove 6.0x50	47178 Hevea-latex surgical glove, non-powdered
31265	Biogel Indicator Uglove 6.5x50	47178 Hevea-latex surgical glove, non-powdered
31270	Biogel Indicator Uglove 7.0x50	47178 Hevea-latex surgical glove, non-powdered
31275	Biogel Indicator Uglove 7.5x50	47178 Hevea-latex surgical glove, non-powdered
31280	Biogel Indicator Uglove 8.0x50	47178 Hevea-latex surgical glove, non-powdered
31285	Biogel Indicator Uglove 8.5x50	47178 Hevea-latex surgical glove, non-powdered
31290	Biogel Indicator U/glove9.0x40	47178 Hevea-latex surgical glove, non-powdered
4482255	Biogel Surgeons 5.5 x25	47178 Hevea-latex surgical glove, non-powdered
4482260	Biogel Surgeons 6.0 x25	47178 Hevea-latex surgical glove, non-powdered
4482265	Biogel Surgeons 6.5 x25	47178 Hevea-latex surgical glove, non-powdered
4482270	Biogel Surgeons 7.0 x25	47178 Hevea-latex surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
4482275	Biogel Surgeons 7.5 x25	47178 Hevea-latex surgical glove, non-powdered
4482280	Biogel Surgeons 8.0 x25	47178 Hevea-latex surgical glove, non-powdered
4482285	Biogel Surgeons 8.5 x25	47178 Hevea-latex surgical glove, non-powdered
4482290	Biogel Surgeons 9.0 x20	47178 Hevea-latex surgical glove, non-powdered
4496155	Biogel Tech 5.5 x 50	47178 Hevea-latex surgical glove, non-powdered
4496160	Biogel Tech 6.0 x 50	47178 Hevea-latex surgical glove, non-powdered
4496165	Biogel Tech 6.5 x 50	47178 Hevea-latex surgical glove, non-powdered
4496170	Biogel Tech 7.0 x 50	47178 Hevea-latex surgical glove, non-powdered
4496175	Biogel Tech 7.5 x 50	47178 Hevea-latex surgical glove, non-powdered
4496180	Biogel Tech 8.0 x 50	47178 Hevea-latex surgical glove, non-powdered
4496185	Biogel Tech 8.5 x 50	47178 Hevea-latex surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
4496190	Biogel Tech 9.0 x 40	47178 Hevea-latex surgical glove, non-powdered
82255	Biogel Surgeons 5.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
82260	Biogel Surgeons 6.0 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
82265	Biogel Surgeons 6.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
82270	Biogel Surgeons 7.0 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
82275	Biogel Surgeons 7.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
82280	Biogel Surgeons 8.0 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
82285	Biogel Surgeons 8.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
82290	Biogel Surgeons 9.0 x40 EUR	47178 Hevea-latex surgical glove, non-powdered
82355	Biogel MicroSurgeons 5.5x50EUR	47178 Hevea-latex surgical glove, non-powdered
82360	Biogel MicroSurgeons 6.0x50EUR	47178 Hevea-latex surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
82365	Biogel MicroSurgeons 6.5x50EUR	47178 Hevea-latex surgical glove, non-powdered
82370	Biogel MicroSurgeons 7.0x50EUR	47178 Hevea-latex surgical glove, non-powdered
82375	Biogel MicroSurgeons 7.5x50EUR	47178 Hevea-latex surgical glove, non-powdered
82380	Biogel MicroSurgeons 8.0x50EUR	47178 Hevea-latex surgical glove, non-powdered
82385	Biogel MicroSurgeons 8.5x50EUR	47178 Hevea-latex surgical glove, non-powdered
82390	Biogel MicroSurgeons 9.0x40EUR	47178 Hevea-latex surgical glove, non-powdered
82555	Biogel Super Sens 5.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
82560	Biogel Super Sens 6.0 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
82565	Biogel Super Sens 6.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
82570	Biogel Super Sens 7.0 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
82575	Biogel Super Sens 7.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered



<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
82580	Biogel Super Sens 8.0 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
82585	Biogel Super Sens 8.5 x50 EUR	47178 Hevea-latex surgical glove, non-powdered
82590	Biogel Super Sens 9.0 x40 EUR	47178 Hevea-latex surgical glove, non-powdered
84255	Biogel IndicatorDD 5.5 2x25EUR	47178 Hevea-latex surgical glove, non-powdered
84260	Biogel IndicatorDD 6.0 2x25EUR	47178 Hevea-latex surgical glove, non-powdered
84265	Biogel IndicatorDD 6.5 2x25EUR	47178 Hevea-latex surgical glove, non-powdered
84270	Biogel IndicatorDD 7.0 2x25EUR	47178 Hevea-latex surgical glove, non-powdered
84275	Biogel IndicatorDD 7.5 2x25EUR	47178 Hevea-latex surgical glove, non-powdered
84280	Biogel IndicatorDD 8.0 2x25EUR	47178 Hevea-latex surgical glove, non-powdered
84285	Biogel IndicatorDD 8.5 2x25EUR	47178 Hevea-latex surgical glove, non-powdered
96155	Biogel Surgeons 5.5 x50 UK	47178 Hevea-latex surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
96160	Biogel Surgeons 6.0 x50 UK	47178 Hevea-latex surgical glove, non-powdered
96165	Biogel Surgeons 6.5 x50 UK	47178 Hevea-latex surgical glove, non-powdered
96170	Biogel Surgeons 7.0 x50 UK	47178 Hevea-latex surgical glove, non-powdered
96175	Biogel Surgeons 7.5 x50 UK	47178 Hevea-latex surgical glove, non-powdered
96180	Biogel Surgeons 8.0 x50 UK	47178 Hevea-latex surgical glove, non-powdered
96185	Biogel Surgeons 8.5 x50 UK	47178 Hevea-latex surgical glove, non-powdered
96190	Biogel Surgeons 9.0 x40 UK	47178 Hevea-latex surgical glove, non-powdered
96255	Biogel Micro Surgeons 5.5x50UK	47178 Hevea-latex surgical glove, non-powdered
96260	Biogel Micro Surgeons 6.0x50UK	47178 Hevea-latex surgical glove, non-powdered
96265	Biogel Micro Surgeons 6.5x50UK	47178 Hevea-latex surgical glove, non-powdered
96270	Biogel Micro Surgeons 7.0x50UK	47178 Hevea-latex surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
96275	Biogel Micro Surgeons 7.5x50UK	47178 Hevea-latex surgical glove, non-powdered
96280	Biogel Micro Surgeons 8.0x50UK	47178 Hevea-latex surgical glove, non-powdered
96285	Biogel Micro Surgeons 8.5x50UK	47178 Hevea-latex surgical glove, non-powdered
96290	Biogel Micro Surgeons 9.0x40UK	47178 Hevea-latex surgical glove, non-powdered
97555	Biogel Super Sens 5.5 x 50 UK	47178 Hevea-latex surgical glove, non-powdered
97560	Biogel Super Sens 6.0 x 50 UK	47178 Hevea-latex surgical glove, non-powdered
97565	Biogel Super Sens 6.5 x 50 UK	47178 Hevea-latex surgical glove, non-powdered
97570	Biogel Super Sens 7.0 x 50 UK	47178 Hevea-latex surgical glove, non-powdered
97575	Biogel Super Sens 7.5 x 50 UK	47178 Hevea-latex surgical glove, non-powdered
97580	Biogel Super Sens 8.0 x 50 UK	47178 Hevea-latex surgical glove, non-powdered
97585	Biogel Super Sens 8.5 x 50 UK	47178 Hevea-latex surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
97590	Biogel Super Sens 9.0 x 40 UK	47178 Hevea-latex surgical glove, non-powdered
9931255	Biogel Indicator Uglove 5.5x50	47178 Hevea-latex surgical glove, non-powdered
9931260	Biogel Indicator Uglove 6.0x50	47178 Hevea-latex surgical glove, non-powdered
9931265	Biogel Indicator Uglove 6.5x50	47178 Hevea-latex surgical glove, non-powdered
9931270	Biogel Indicator Uglove 7.0x50	47178 Hevea-latex surgical glove, non-powdered
9931275	Biogel Indicator Uglove 7.5x50	47178 Hevea-latex surgical glove, non-powdered
9931280	Biogel Indicator Uglove 8.0x50	47178 Hevea-latex surgical glove, non-powdered
9931285	Biogel Indicator Uglove 8.5x50	47178 Hevea-latex surgical glove, non-powdered
9931290	Biogel Indicator Uglove 9.0x40	47178 Hevea-latex surgical glove, non-powdered