



We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being exclusively responsible manufacturer for conformity of the following, declare that the PPE listed in the attached schedule are in conformity with the provisions of the REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC

Trade name / Product name:	Biogel
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Product classification: III

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: Annex VII (Module C2)	
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Certificate number:	CE 699813	
Issued by:	BSi	Id No: 0086
	(Notified Body Name)	(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: 17-July-2019

Function: REGULATORY AFFAIRS
MANAGER

Name: VICTORIA STEAD

Signature: VJ Stead

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Title: Declaration of Conformity Declaration of Conformity PPE dual certified gloves

Product Reference:	Product Descriptor:
75155	Biogel Eclipse
75160	Biogel Eclipse
75165	Biogel Eclipse
75170	Biogel Eclipse
75175	Biogel Eclipse
75180	Biogel Eclipse
75185	Biogel Eclipse
75190	Biogel Eclipse

Product Reference:	Product Descriptor:
60755	Biogel Eclipse Indicator System
60760	Biogel Eclipse Indicator System
60765	Biogel Eclipse Indicator System
60770	Biogel Eclipse Indicator System
60775	Biogel Eclipse Indicator System
60780	Biogel Eclipse Indicator System
60785	Biogel Eclipse Indicator System

Product Reference:	Product Descriptor:
73255	Biogel Eclipse Indicator Underglove
73260	Biogel Eclipse Indicator Underglove
73265	Biogel Eclipse Indicator Underglove
73270	Biogel Eclipse Indicator Underglove
73275	Biogel Eclipse Indicator Underglove
73280	Biogel Eclipse Indicator Underglove
73285	Biogel Eclipse Indicator Underglove
73290	Biogel Eclipse Indicator Underglove

Product Reference:	Product Descriptor:
82255	Biogel Surgeons

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82260	Biogel Surgeons
82265	Biogel Surgeons
82270	Biogel Surgeons
82275	Biogel Surgeons
82280	Biogel Surgeons
82285	Biogel Surgeons
82290	Biogel Surgeons

Product Reference:	Product Descriptor:
96155	Biogel Surgeons
96160	Biogel Surgeons
96165	Biogel Surgeons
96170	Biogel Surgeons
96175	Biogel Surgeons
96180	Biogel Surgeons
96185	Biogel Surgeons
96190	Biogel Surgeons

Product Reference:	Product Descriptor:
82555	Biogel SuperSensitive
82560	Biogel SuperSensitive
82565	Biogel SuperSensitive
82570	Biogel SuperSensitive
82575	Biogel SuperSensitive
82580	Biogel SuperSensitive
82585	Biogel SuperSensitive
82590	Biogel SuperSensitive

Product Reference:	Product Descriptor:
84255	Biogel Indicator System
84260	Biogel Indicator System

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84265	Biogel Indicator System
84270	Biogel Indicator System
84275	Biogel Indicator System
84280	Biogel Indicator System
84285	Biogel Indicator System

Product Reference:	Product Descriptor:
40955	Biogel PI UltraTouch
40960	Biogel PI UltraTouch
40965	Biogel PI UltraTouch
40970	Biogel PI UltraTouch
40975	Biogel PI UltraTouch
40980	Biogel PI UltraTouch
40985	Biogel PI UltraTouch
40990	Biogel PI UltraTouch

Product Reference:	Product Descriptor:
41455	Biogel PI Indicator System
41460	Biogel PI Indicator System
41465	Biogel PI Indicator System
41470	Biogel PI Indicator System
41475	Biogel PI Indicator System
41480	Biogel PI Indicator System
41485	Biogel PI Indicator System

Product Reference:	Product Descriptor:
41655	Biogel PI Indicator Underglove
41660	Biogel PI Indicator Underglove
41665	Biogel PI Indicator Underglove
41670	Biogel PI Indicator Underglove
41675	Biogel PI Indicator Underglove
41680	Biogel PI Indicator Underglove

41685	Biogel PI Indicator Underglove
41690	Biogel PI Indicator Underglove

Product Reference:	Product Descriptor:
48555	Biogel PI Micro
48560	Biogel PI Micro
48565	Biogel PI Micro
48570	Biogel PI Micro
48575	Biogel PI Micro
48580	Biogel PI Micro
48585	Biogel PI Micro
48590	Biogel PI Micro

Product Reference:	Product Descriptor:
48355	Biogel PI Micro Indicator System
48360	Biogel PI Micro Indicator System
48365	Biogel PI Micro Indicator System
48370	Biogel PI Micro Indicator System
48375	Biogel PI Micro Indicator System
48380	Biogel PI Micro Indicator System
48385	Biogel PI Micro Indicator System

Product Reference:	Product Descriptor:
48955	Biogel PI Micro Indicator Underglove
48960	Biogel PI Micro Indicator Underglove
48965	Biogel PI Micro Indicator Underglove
48970	Biogel PI Micro Indicator Underglove
48975	Biogel PI Micro Indicator Underglove
48980	Biogel PI Micro Indicator Underglove
48985	Biogel PI Micro Indicator Underglove
48990	Biogel PI Micro Indicator Underglove

Product Reference:	Product Descriptor:
50955	Biogel Skinsense
50960	Biogel Skinsense
50965	Biogel Skinsense
50970	Biogel Skinsense
50975	Biogel Skinsense
50980	Biogel Skinsense
50985	Biogel Skinsense
50990	Biogel Skinsense

Product Reference:	Product Descriptor:
28855	Biogel Skinsense Indicator System
28860	Biogel Skinsense Indicator System
28865	Biogel Skinsense Indicator System
28870	Biogel Skinsense Indicator System
28875	Biogel Skinsense Indicator System
28880	Biogel Skinsense Indicator System
28885	Biogel Skinsense Indicator System

Product Reference:	Product Descriptor:
40655	Biogel Skinsense Indicator Underglove
40660	Biogel Skinsense Indicator Underglove
40665	Biogel Skinsense Indicator Underglove
40670	Biogel Skinsense Indicator Underglove
40675	Biogel Skinsense Indicator Underglove
40680	Biogel Skinsense Indicator Underglove
40685	Biogel Skinsense Indicator Underglove
40690	Biogel Skinsense Indicator Underglove

Product Reference:	Product Descriptor:
3350955	Biogel Skinsense (non sterile)
3350960	Biogel Skinsense (non sterile)

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3350965	Biogel Skinsense (non sterile)
3350970	Biogel Skinsense (non sterile)
3350975	Biogel Skinsense (non sterile)
3350980	Biogel Skinsense (non sterile)
3350985	Biogel Skinsense (non sterile)
3350990	Biogel Skinsense (non sterile)

Product Reference:	Product Descriptor:
3340655	Biogel Skinsense Indicator Underglove (non sterile)
3340660	Biogel Skinsense Indicator Underglove (non sterile)
3340665	Biogel Skinsense Indicator Underglove (non sterile)
3340670	Biogel Skinsense Indicator Underglove (non sterile)
3340675	Biogel Skinsense Indicator Underglove (non sterile)
3340680	Biogel Skinsense Indicator Underglove (non sterile)
3340685	Biogel Skinsense Indicator Underglove (non sterile)
3340690	Biogel Skinsense Indicator Underglove (non sterile)

Product Reference:	Product Descriptor:
45555	Biogel PI UltraTouch S
45560	Biogel PI UltraTouch S
45565	Biogel PI UltraTouch S
45570	Biogel PI UltraTouch S
45575	Biogel PI UltraTouch S
45580	Biogel PI UltraTouch S
45585	Biogel PI UltraTouch S
45590	Biogel PI UltraTouch S

Product Reference:	Product Descriptor:
45355	Biogel PI UltraTouch S Indicator System
45360	Biogel PI UltraTouch S Indicator System
45365	Biogel PI UltraTouch S Indicator System
45370	Biogel PI UltraTouch S Indicator System

45375	Biogel PI UltraTouch S Indicator System
45380	Biogel PI UltraTouch S Indicator System
45385	Biogel PI UltraTouch S Indicator System

Product Reference:	Product Descriptor:
45955	Biogel PI UltraTouch S Indicator Underglove
45960	Biogel PI UltraTouch S Indicator Underglove
45965	Biogel PI UltraTouch S Indicator Underglove
45970	Biogel PI UltraTouch S Indicator Underglove
45975	Biogel PI UltraTouch S Indicator Underglove
45980	Biogel PI UltraTouch S Indicator Underglove
45985	Biogel PI UltraTouch S Indicator Underglove
45990	Biogel PI UltraTouch S Indicator Underglove

Mölnlycke Health Care operates a quality system that is certified to:

ISO 9001:2015 Quality Management Systems. Requirements

ISO 13485:2016 and EN ISO 13485:2016. Medical Devices, Quality Management Systems. Requirements for Regulatory Purposes

ISO 14001:2015 Environmental Management Systems – Requirements with guidance for use

EN 420:2004+A1:2009 Protective gloves – General requirements and test methods

EN ISO 374-1:2016/A1:2018 Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks

EN 374-2:2014 Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration

EN 374-4:2013 Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals

EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks

EN 16523-1:2015 Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

EN 455-1:2000 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes

EN 455-2:2015 Medical gloves for single use - Part 2: Requirements and testing for physical properties

EN 455-3:2015 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation

EN 455-4:2009 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination

EN ISO 14971: 2012 Medical Devices – Application of risk management to medical devices (and with reference to ISO 10993 – Biological evaluation of Medical Devices)

EN ISO 15223-1: 2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied.

EN ISO 11137-1:2015: Sterilisation of health care products – Radiation Part 1: Requirements for development, validation and routine control of a sterilisation process for medical devices.

EN ISO 11137-2:2015: Sterilisation of health care products – Radiation Part 2: Establishing the sterilisation dose.

EN ISO 11737-1:2006/AC:2009: Sterilisation of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products.

EN 556-1:2001/AC:2006 – Sterilisation of Medical Devices – Requirements for medical devices to be designated “STERILE”. Requirements for terminally sterilised medical devices.

EN ISO 10993-1:2009/AC:2010: Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process.

EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

EN ISO 10993-10:2013 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

ASTM F1671/F1671M:2013 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

ISO 16604:2004 Clothing for protection against contact with blood and body fluids - Determination of resistance of protective clothing materials to penetration by blood-borne pathogens - Test method using Phi-X 174 bacteriophage

USP 151 Pyrogenicity Test

All documents of relevance to the CE marking Personal Protective Equipment are controlled according to Standard Procedures which form part of the quality system in alignment with the requirements of the Personal Protective Equipment