Declaration of Conformity for Devices under the PPE Regulation

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Title: EU PPE Declaration of Conformity Dual certified gloves

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being exclusively the responsible manufacturer for conformity of the following, declare that the Personal Protective Equipment (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:	PPE Dual Certified Gloves

Product classification: Category III

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: V & VII

Certificate number: CE 699813

Issued by: BSi (Notified Body Name) Id No: 2797 (Notified Body)

Notified Body Address: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands

Mölnlycke Health Care AB issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care AB

Date: 10-JAN-2022 Function: REGULATORY AFFAIRS MANAGER

Name: VICTORIA STEAD Signature: VStead

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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
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
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
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
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
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
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
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

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
50955	Biogel Skinsense
50960	Biogel Skinsense
50965	Biogel Skinsense
50970	Biogel Skinsense
50975	Biogel Skinsense
50980	Biogel Skinsense
50985	Biogel Skinsense
50990	Biogel Skinsense
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
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

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)
75155	Biogel Eclipse
75160	Biogel Eclipse
75165	Biogel Eclipse
75170	Biogel Eclipse
75175	Biogel Eclipse
75180	Biogel Eclipse
75185	Biogel Eclipse
75190	Biogel Eclipse
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
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

82255	Biogel Surgeons
82260	Biogel Surgeons
82265	Biogel Surgeons
82270	Biogel Surgeons
82275	Biogel Surgeons
82280	Biogel Surgeons
82285	Biogel Surgeons
82290	Biogel Surgeons
96155	Biogel Surgeons
96160	Biogel Surgeons
96165	Biogel Surgeons
96170	Biogel Surgeons
96175	Biogel Surgeons
96180	Biogel Surgeons
96185	Biogel Surgeons
96190	Biogel Surgeons
82555	Biogel Super-Sensitive
82560	Biogel Super-Sensitive
82565	Biogel Super-Sensitive
82570	Biogel Super-Sensitive
82575	Biogel Super-Sensitive
82580	Biogel Super-Sensitive
82585	Biogel Super-Sensitive
82590	Biogel Super-Sensitive
84255	Biogel Indicator System
84260	Biogel Indicator System
84265	Biogel Indicator System
84270	Biogel Indicator System
84275	Biogel Indicator System
84280	Biogel Indicator System
84285	Biogel Indicator System

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List of Harmonised Standards

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

EN ISO 9001: 2008 Quality Management Systems. Requirements

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 ISO 21420:2020: 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 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration

EN 374-4:2019 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+A1:2018 Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

EN 455-1:2020 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 10993-1:2018: 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

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 11737-1:2018: 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.

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

ASTM D3577-19: Standard Specification for Rubber Surgical Gloves

ASTM D6978-05: Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

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 Regulation (EU) 2016/425

List of Harmonised Standards