Title: EU Declaration of Conformity PPE Critical Environment 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 Tech Gloves

Product classification: Category III

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

Certificate number: CE 687999

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: 04 August 2021 Function: Regulatory Affairs Manager

Name: Victoria Stead Signature: _____

Title: EU Declaration of Conformity PPE Critical Environment Gloves

Product Reference:	Product Descriptor:
4450955	Biogel Neotech
4450960	Biogel Neotech
4450965	Biogel Neotech
4450970	Biogel Neotech
4450975	Biogel Neotech
4450980	Biogel Neotech
4450985	Biogel Neotech
4450990	Biogel Neotech
4482255	Biogel Tech
4482260	Biogel Tech
4482265	Biogel Tech
4482270	Biogel Tech
4482275	Biogel Tech
4482280	Biogel Tech
4482285	Biogel Tech
4482290	Biogel Tech
4496155	Biogel Tech
4496160	Biogel Tech
4496165	Biogel Tech
4496170	Biogel Tech
4496175	Biogel Tech
4496180	Biogel Tech
4496185	Biogel Tech
4496190	Biogel Tech
4440955	Biogel PI Tech
4440960	Biogel PI Tech
4440965	Biogel PI Tech
4440970	Biogel PI Tech
4440975	Biogel PI Tech
4440980	Biogel PI Tech

4440985	Biogel PI Tech
4440990	Biogel PI Tech
4441655	Biogel PI Tech Indicator Underglove
4441660	Biogel PI Tech Indicator Underglove
4441665	Biogel PI Tech Indicator Underglove
4441670	Biogel PI Tech Indicator Underglove
4441675	Biogel PI Tech Indicator Underglove
4441680	Biogel PI Tech Indicator Underglove
4441685	Biogel PI Tech Indicator Underglove
4441690	Biogel PI Tech Indicator Underglove
4440655	Biogel NeoTech Indicator Underglove
4440660	Biogel NeoTech Indicator Underglove
4440665	Biogel NeoTech Indicator Underglove
4440670	Biogel NeoTech Indicator Underglove
4440675	Biogel NeoTech Indicator Underglove
4440680	Biogel NeoTech Indicator Underglove
4440685	Biogel NeoTech Indicator Underglove
4440690	Biogel NeoTech Indicator Underglove
4448555	Biogel PI Micro Tech
4448560	Biogel PI Micro Tech
4448565	Biogel PI Micro Tech
4448570	Biogel PI Micro Tech
4448575	Biogel PI Micro Tech
4448580	Biogel PI Micro Tech
4448585	Biogel PI Micro Tech
4448590	Biogel PI Micro Tech
4448955	Biogel PI Micro Tech Indicator Underglove
4448960	Biogel PI Micro Tech Indicator Underglove
4448965	Biogel PI Micro Tech Indicator Underglove
4448970	Biogel PI Micro Tech Indicator Underglove
4448975	Biogel PI Micro Tech Indicator Underglove

Title: EU Declaration of Conformity PPE Critical Environment Gloves

4448980	Biogel PI Micro Tech Indicator Underglove
4448985	Biogel PI Micro Tech Indicator Underglove
4448990	Biogel PI Micro Tech Indicator Underglove

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

Title: EU Declaration of Conformity PPE Critical Environment Gloves

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