DECLARATION OF CONFORMITY

replaces version dated: 15.06.2021

We

OneMed Group Oy, Metsäläntie 20, FI-00320 Helsinki
SRN FI-MF-000000642

declare under our sole responsibility that following CE marked products, all belonging to

- **class I** according to Annex VIII of the **Regulation (EU) 2017/745 on medical devices,** and to
- **category III** according to the **Regulation (EU) 2016/425 on personal protective equipment**

Intended Purpose:
Nitrile examination gloves are for medical purposes intended to be worn on care giver's hands to prevent cross-contamination between care giver and a patient. The gloves are non-sterile. The gloves are for single use. The device may be used by health care professional or lay person.

Basic UDI-DI: 6438129B0001GU

Item number (REF)	Trade and product name
6420	**evercare® Nitrile Medical Exam Gloves SAFE X-LONG, blue, AQL 1.0, size XS**
6421	**evercare® Nitrile Medical Exam Gloves SAFE X-LONG, blue, AQL 1.0, size S**
6422	**evercare® Nitrile Medical Exam Gloves SAFE X-LONG, blue, AQL 1.0, size M**
6423	**evercare® Nitrile Medical Exam Gloves SAFE X-LONG, blue, AQL 1.0, size L**
6424	**evercare® Nitrile Medical Exam Gloves SAFE X-LONG, blue, AQL 1.0, size XL**

to which this declaration relates, are in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices as well as of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment, and with following standards and common specifications[1]:

EN ISO 13485	Medical Devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971	Medical Devices – Application of risk management to medical devices
EN 1041	Information supplied by the manufacturer with medical devices
EN ISO 15223-1	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements
EN 420	Protective glove. General requirements and test method
EN 455-1	Medical gloves for single use. Part 1 – Requirements and testing for freedom from holes
EN 455-2	Medical gloves for single use. Part 2 – Requirements and testing for physical properties
EN 455-3	Medical gloves for single use. Part 3 – Requirements and testing for biological evaluation
EN 455-4	Medical gloves for single use. Part 4 – Requirements and testing for shelf life determination
EN ISO 374-1	Protective gloves against chemicals and micro-organism. Part 1 - Terminology and performance requirements for chemical risks
EN ISO 374-5	Protective gloves against dangerous chemicals and micro-organisms. Part 5 - Terminology and performance requirements for micro-organisms risks

[1]Latest applied revisions of regulations, standards and common specifications are presented in T-079 Review of regulations and standards

The product(s) is (are) subject to the conformity assessment procedure Module C2 under surveillance of the notified body 2777 SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland. EU Type Examination certificate 2777/10922-02/E01-01. Type B glove according to EN 374-1:2016.

Place and date of issue

Göteborg 22.06.2022

Name and signature of the authorized person

Martin Hillbratt
Quality and Regulatory Director
OneMed Group Oy