

DECLARATION OF CONFORMITY

replaces version dated: 15.06.2021

We

OneMed Group Oy, Metsäläntie 20, FI-00320 Helsinki
SRN FI-MF-00000642

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
6400	evercare® Nitrile Medical Exam Gloves SKY, blue, AQL 1.0, size XS
6401	evercare® Nitrile Medical Exam Gloves SKY, blue, AQL 1.0, size S
6402	evercare® Nitrile Medical Exam Gloves SKY, blue, AQL 1.0, size M
6403	evercare® Nitrile Medical Exam Gloves SKY, blue, AQL 1.0, size L
6404	evercare® Nitrile Medical Exam Gloves SKY, blue, AQL 1.0, size XL
6405	evercare® Nitrile Medical Exam Gloves ROSA, pink, size XS
6406	evercare® Nitrile Medical Exam Gloves ROSA, pink, size S
6407	evercare® Nitrile Medical Exam Gloves ROSA, pink, size M
6408	evercare® Nitrile Medical Exam Gloves ROSA, pink, size L
6409	evercare® Nitrile Medical Exam Gloves ROSA, pink, size XL
6415	evercare® Nitrile Medical Exam Gloves SVEA, blue/lilac, AQL 1.0, size XS
6416	evercare® Nitrile Medical Exam Gloves SVEA, blue/lilac, AQL 1.0, size S
6417	evercare® Nitrile Medical Exam Gloves SVEA, blue/lilac, AQL 1.0, size M
6418	evercare® Nitrile Medical Exam Gloves SVEA, blue/lilac, AQL 1.0, size L
6419	evercare® Nitrile Medical Exam Gloves SVEA, blue/lilac, AQL 1.0, size XL
6425	evercare® Nitrile Medical Exam Gloves FROST, white, AQL 1.0, size XS
6426	evercare® Nitrile Medical Exam Gloves FROST, white, AQL 1.0, size S
6427	evercare® Nitrile Medical Exam Gloves FROST, white, AQL 1.0, size M
6428	evercare® Nitrile Medical Exam Gloves FROST, white, AQL 1.0, size L
6429	evercare® Nitrile Medical Exam Gloves FROST, white, AQL 1.0, size XL
6490	evercare® Nitrile Medical Exam Gloves SATIN, white, size XS
6491	evercare® Nitrile Medical Exam Gloves SATIN, white, size S
6492	evercare® Nitrile Medical Exam Gloves SATIN, white, size M
6493	evercare® Nitrile Medical Exam Gloves SATIN, white, size L
6494	evercare® Nitrile Medical Exam Gloves SATIN, white, size XL
6495	evercare® Nitrile Medical Exam Gloves SMOOTH, grey, size XS
6496	evercare® Nitrile Medical Exam Gloves SMOOTH, grey, size S
6497	evercare® Nitrile Medical Exam Gloves SMOOTH, grey, size M
6498	evercare® Nitrile Medical Exam Gloves SMOOTH, grey, size L
6499	evercare® Nitrile Medical Exam Gloves SMOOTH, grey, size XL
6520	evercare® Nitrile Medical Exam Gloves SATIN X-LONG, white, size XS
6521	evercare® Nitrile Medical Exam Gloves SATIN X-LONG, white, size S
6522	evercare® Nitrile Medical Exam Gloves SATIN X-LONG, white, size M

6523
6524**evercare® Nitrile Medical Exam Gloves SATIN X-LONG, white, size L**
evercare® Nitrile Medical Exam Gloves SATIN X-LONG, white, 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 specifications¹:

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

¹Latest 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 2777/10893-03/E02-01. 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