

DECLARATION OF CONFORMITY

Replaces version dated:
28.05.2024

Valid until the issue of next version
of this document.

We,

OneMed Group Oy,
Metsäläntie 20,
FI-00320 Helsinki, Finland,

SRN FI-MF-000000642,

Domicile Helsinki,
Business ID 2039640-1,

declare under our sole responsibility that following products 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 Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Classification:

Class I according to Annex VIII of the **Regulation (EU) 2017/745 on medical devices,**

Category III according to the **Regulation (EU) 2016/425 on personal protective equipment**

Intended Purpose (As per Regulation (EU) 2017/745 on medical devices) :

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.

List of devices under Basic UDI-DI 6438129B0001GU:

Item number (REF)	Product name
6400	evercare [®] Nitrile Medical Exam Gloves, blue, AQL 1.0, SKY, size XS
6401	evercare [®] Nitrile Medical Exam Gloves, blue, AQL 1.0, SKY, size S
6402	evercare [®] Nitrile Medical Exam Gloves, blue, AQL 1.0, SKY, size M
6403	evercare [®] Nitrile Medical Exam Gloves, blue, AQL 1.0, SKY, size L
6404	evercare [®] Nitrile Medical Exam Gloves, blue, AQL 1.0, SKY, size XL
6405	evercare [®] Nitrile Medical Exam Gloves, pink, ROSA, size XS
6406	evercare [®] Nitrile Medical Exam Gloves, pink, ROSA, size S
6407	evercare [®] Nitrile Medical Exam Gloves, pink, ROSA, size M
6408	evercare [®] Nitrile Medical Exam Gloves, pink, ROSA, size L
6409	evercare [®] Nitrile Medical Exam Gloves, pink, ROSA, size XL
6415	evercare [®] Nitrile Medical Exam Gloves, blue/lilac, AQL 1.0, SVEA, size XS
6416	evercare [®] Nitrile Medical Exam Gloves, blue/lilac, AQL 1.0, SVEA, size S
6417	evercare [®] Nitrile Medical Exam Gloves, blue/lilac, AQL 1.0, SVEA, size M
6418	evercare [®] Nitrile Medical Exam Gloves, blue/lilac, AQL 1.0, SVEA, size L
6419	evercare [®] Nitrile Medical Exam Gloves, blue/lilac, AQL 1.0, SVEA, size XL
6425	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, FROST, size XS
6426	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, FROST, size S
6427	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, FROST, size M
6428	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, FROST, size L
6429	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, FROST, size XL
6490	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, SATIN, size XS

6491	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, SATIN, size S
6492	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, SATIN, size M
6493	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, SATIN, size L
6494	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, SATIN, size XL
6520	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, SATIN X-LONG, size XS
6521	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, SATIN X-LONG size S
6522	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, SATIN X-LONG, size M
6523	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, SATIN X-LONG, size L
6524	evercare [®] Nitrile Medical Exam Gloves, white, AQL 1.0, SATIN X-LONG, size XL

These items are in conformity with following European 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 ISO 20417	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 374-2	Protective gloves against dangerous chemicals and micro-organism – Part 2: Determination of resistance to penetration
EN ISO 374-4	Protective gloves against dangerous chemicals and micro-organism – Part 4: Determination of resistance to degradation by chemicals
EN ISO 374-5	Protective gloves against dangerous chemicals and micro-organisms. Part 5 - Terminology and performance requirements for micro-organisms risks
EN 16523-1	Determination of material resistance to permeation by chemicals. Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact

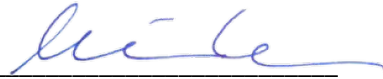
¹Relevant standards, latest applied revisions and common specifications are listed in GEN-079 *Review of regulations and standards*

The notified body 2777, SATRA Technology Europe Limited Bracetown, Business Park, Clonee, D15YN2P, Republic of Ireland performed the EU type-examination (Module B) and issued the EU type-examination certificate 2777/10893-03/E02-01. The product(s) is (are) subject to the conformity assessment procedure Module C2 under surveillance of the same notified body. Type B glove according to EN 374-1:2016.

Place and date of issue

Helsinki 09.07.2025

Name and signature of the authorized person



Hilleriikka Vaho
Regulatory Affairs Manager
OneMed Group Oy

For Reference Only