COMPANY WITH
QUALITY SYSTEM
CERTIFIED BY DNV
ISO 13485

evercare® medical

DECLARATION OF CONFORMITY

Replaces version dated: -

We,

OneMed Group Oy, **SRN** FI-MF-000000642, Domicile Helsinki,
Metsäläntie 20, Business ID 2039640-1,
FI-00320 Helsinki, Finland,

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:

Latex 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 6438129B0003GY:

Item number (REF)	Product name
100035	Embra® Latex Medical Exam Gloves, Natural White, Powder-free, Flex, size XS
100036	Embra® Latex Medical Exam Gloves, Natural White, Powder-free, Flex, size S
100037	Embra® Latex Medical Exam Gloves, Natural White, Powder-free, Flex, size M
100038	Embra® Latex Medical Exam Gloves, Natural White, Powder-free, Flex, size L
100039	Embra® Latex Medical Exam Gloves, Natural White, Powder-free, Flex, size XL

These items are in conformity with following European 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 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 ISO 21420	Protective gloves. General requirements and test methods
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

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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

[1]Latest applied revisions of regulations, standards and common specifications are presented in *T-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 2777/21024-02/E20-01. The products are subject to the conformity assessment procedure Module D under surveillance of the same notified body. Type B glove according to EN ISO 374-1:2016+A1:2018

Place and date of issue Helsinki 04.05.2026

Name and signature of the authorized person

Hilleriikka Vaho
Regulatory Affairs Manager
OneMed Group Oy

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