COMPANY WITH
QUALITY SYSTEM
CERTIFIED BY DNV
ISO 13485

evercare medical

DECLARATION OF CONFORMITY

Replaces version dated:
11.10.2023 (AQUA)
06.11.2023 (CORE)
Valid until the issue of next version of this document.

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 (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:

REF	Product name
6011055	SELEFA® Nitrile Medical Exam gloves, Blue, AQUA, size XS
6011065	SELEFA® Nitrile Medical Exam gloves, Blue, AQUA, size S
6011075	SELEFA® Nitrile Medical Exam gloves, Blue, AQUA, size M
6011085	SELEFA® Nitrile Medical Exam gloves, Blue, AQUA, size L
6011095	SELEFA® Nitrile Medical Exam gloves, Blue, AQUA, size XL
210263XS	SELEFA® Nitrile Exam Gloves, powder-free, Blue, CORE, size XS
210263S	SELEFA® Nitrile Exam Gloves, powder-free, Blue, CORE, size S
210263M	SELEFA® Nitrile Exam Gloves, powder-free, Blue, CORE, size M
210263L	SELEFA® Nitrile Exam Gloves, powder-free, Blue, CORE, size L
210263XL	SELEFA® Nitrile Exam Gloves, powder-free, Blue, CORE, 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
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]Relevant standards, latest applied revisions and common specifications are listed 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 03.01.2024

Name and signature of the authorized person

Hilleriikka Vaho
Regulatory Manager
OneMed Group Oy