

DECLARATION OF CONFORMITY

Replaces version dated:

13.06.2023

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 CE marked products, all belonging to

Classification:

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

Basic UDI-DI

6438129B0001GU

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.

List of devices:

Item number (REF)	Product name
711000	Embra® Nitrile Medical Exam Gloves, Accelerator-free, Green, AQL 1.0, PROCEED, size XS
711001	Embra® Nitrile Medical Exam Gloves, Accelerator-free, Green, AQL 1.0, PROCEED, size S
711002	Embra® Nitrile Medical Exam Gloves, Accelerator-free, Green, AQL 1.0, PROCEED, size M
711003	Embra® Nitrile Medical Exam Gloves, Accelerator-free, Green, AQL 1.0, PROCEED, size L
711004	Embra® Nitrile Medical Exam Gloves, Accelerator-free, Green, AQL 1.0, PROCEED, size XL
711005	Embra® Nitrile Medical Exam Gloves, Accelerator-free, Green, AQL 1.0, PROCEED X-LONG, size XS
711006	Embra® Nitrile Medical Exam Gloves, Accelerator-free, Green, AQL 1.0, PROCEED X-LONG, size S
711007	Embra® Nitrile Medical Exam Gloves, Accelerator-free, Green, AQL 1.0, PROCEED X-LONG, size M
711008	Embra® Nitrile Medical Exam Gloves, Accelerator-free, Green, AQL 1.0, PROCEED X-LONG, size L
711009	Embra® Nitrile Medical Exam Gloves, Accelerator-free, Green, AQL 1.0, PROCEED 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 ISO 21420	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 and latest applied revisions are listed in *T-079 Review of regulation 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 2777/17317-02/E01-02. The products 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 06.11.2023

Name and signature of the authorized person



Hilleriikka Vaho
Regulatory Manager
OneMed Group Oy