DECLARATION OF CONFORMITY

replaces version dated: 01.07.2020

We

OneMed Group Oy, Metsäläntie 20, FI-00320 Helsinki
SRN FI-MF-000000642

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**

Basic UDI-DI	**6438129B0001GU**
Item number (REF)	**Trade and product name**
210252 sizes XS, S, M, L, XL	**SELEFA® Nitrile exam gloves, SMART, white (200 pcs)**
210253 sizes XS, S, M, L, XL	**SELEFA® Nitrile exam gloves, SMART, blue (200 pcs)**
210255 sizes XS, S, M, L, XL	**SELEFA® Nitrile exam gloves, SMART, blue (100 pcs)**
210256 sizes XS, S, M, L, XL	**SELEFA® Nitrile exam gloves, SMART, white (150 pcs)**
210258 sizes XS, S, M, L, XL	**SELEFA® Nitrile exam gloves, SENSE, blue (200 pcs)**
210259 sizes XS, S, M, L, XL	**SELEFA® Nitrile exam gloves, SENSE, black (200 pcs)**

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 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 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

[1]Latest applied revisions of regulations, standards and common specifications in T-079 Review of regulations and standards

The products are subject to the conformity assessment procedure conformity to type based on Module C2 under surveillance of the notified body **2777 SATRA Technology Europe Limited, Bracetown Business**

Park, Clonee, D15YN2P, Republic of Ireland, and issued the EU Type Examination certificate 2777/10892-02/E02-01. Type C glove according to EN 374-1:2016.

Place and date of issue

Göteborg 15.06.2021

Name and signature of the authorized person

Martin Hillbratt
Quality Director