

# 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
<b>6420</b>	<b>evercare® Nitrile Exam gloves SAFE X-LONG, blue, AQL 1.0, size XS</b>
<b>6421</b>	<b>evercare® Nitrile Exam gloves SAFE X-LONG, blue, AQL 1.0, size S</b>
<b>6422</b>	<b>evercare® Nitrile Exam gloves SAFE X-LONG, blue, AQL 1.0, size M</b>
<b>6423</b>	<b>evercare® Nitrile Exam gloves SAFE X-LONG, blue, AQL 1.0, size L</b>
<b>6424</b>	<b>evercare® Nitrile Exam gloves SAFE X-LONG, blue, AQL 1.0, size XL</b>

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<sup>1</sup>:

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

<sup>1</sup>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 2777/10922-02/E01-01. Type B 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

For Reference Only