

DECLARATION OF CONFORMITY

replaces version dated: 25.04.2019

We

OneMed Group Oy, Metsäläntie 20, FI-00320 Helsinki

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 64381290006GN00000T7

Item number (REF) Trade and product name

6400	evercare® Nitrile Exam gloves SKY, blue, AQL 1.0, size XS
6401	evercare® Nitrile Exam gloves SKY, blue, AQL 1.0, size S
6402	evercare® Nitrile Exam gloves SKY, blue, AQL 1.0, size M
6403	evercare® Nitrile Exam gloves SKY, blue, AQL 1.0, size L
6404	evercare® Nitrile Exam gloves SKY, blue, AQL 1.0, size XL
6405	evercare® Nitrile Exam gloves ROSA, pink, size XS
6406	evercare® Nitrile Exam gloves ROSA, pink, size S
6407	evercare® Nitrile Exam gloves ROSA, pink, size M
6408	evercare® Nitrile Exam gloves ROSA, pink, size L
6409	evercare® Nitrile Exam gloves ROSA, pink, size XL
6415	evercare® Nitrile Exam gloves SVEA, blue/lilac, AQL 1.0, size XS
6416	evercare® Nitrile Exam gloves SVEA, blue/lilac, AQL 1.0, size S
6417	evercare® Nitrile Exam gloves SVEA, blue/lilac, AQL 1.0, size M
6418	evercare® Nitrile Exam gloves SVEA, blue/lilac, AQL 1.0, size L
6419	evercare® Nitrile Exam gloves SVEA, blue/lilac, AQL 1.0, size XL
6425	evercare® Nitrile Exam gloves FROST, white, AQL 1.0, size XS
6426	evercare® Nitrile Exam gloves FROST, white, AQL 1.0, size S
6427	evercare® Nitrile Exam gloves FROST, white, AQL 1.0, size M
6428	evercare® Nitrile Exam gloves FROST, white, AQL 1.0, size L
6429	evercare® Nitrile Exam gloves FROST, white, AQL 1.0, size XL
6490	evercare® Nitrile Exam gloves SATIN, white, size XS
6491	evercare® Nitrile Exam gloves SATIN, white, size S
6492	evercare® Nitrile Exam gloves SATIN, white, size M
6493	evercare® Nitrile Exam gloves SATIN, white, size L
6494	evercare® Nitrile Exam gloves SATIN, white, size XL
6495	evercare® Nitrile Exam gloves SMOOTH, grey, size XS
6496	evercare® Nitrile Exam gloves SMOOTH, grey, size S
6497	evercare® Nitrile Exam gloves SMOOTH, grey, size M
6498	evercare® Nitrile Exam gloves SMOOTH, grey, size L
6499	evercare® Nitrile Exam gloves SMOOTH, grey, size XL
6520	evercare® Nitrile Exam gloves SATIN X-LONG, white, size XS
6521	evercare® Nitrile Exam gloves SATIN X-LONG, white, size S
6522	evercare® Nitrile Exam gloves SATIN X-LONG, white, size M
6523	evercare® Nitrile Exam gloves SATIN X-LONG, white, size L
6524	evercare® Nitrile Exam gloves SATIN X-LONG, white, size XL

OneMed Group Oy
Address: Metsäläntie 20
FI-00321 Helsinki, Finland

Phone +358 20 786 6800
www.onemed.com

Domicile Helsinki
Business ID 2039640-1

1 (2)

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 harmonized 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 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 -
EN ISO 374-5	Protective gloves against dangerous chemicals and micro-organisms. Part 5 - Terminology and performance requirements for micro-organisms risks

¹Relevant harmonized standards with latest applied revisions listed in Appendix 1

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 2777/10893-03/E02-01.

Place and date of issue

Malmö 15.05.2020

Name and signature of the authorized person



Julien Rolland
Business Area and Sourcing Director

Appendix 1

evercare® and SELEFA® Nitrile examination gloves

Harmonized standards

EN ISO 13485:2016/AC:2018

EN ISO 14971:2012

EN 1041:2008

EN ISO 15223-1:2016

EN 420:2003+A1:2009

EN 455-1:2000

EN 455-2:2009 +A2:2013

EN 455-3:2006

EN 455-4:2009

EN ISO 374-1:2016

EN ISO 374-5:2016

Applicable non-harmonized standards

EN 455-2:2015

EN 455-3:2015

EN ISO 374-2:2015

EN 374-3:2003

EN 374-4:2013

EN 16523-1:2015+A1:2018