COMPANY WITH
QUALITY SYSTEM
CERTIFIED BY DNV
ISO 13485

evercare® medical

DECLARATION OF CONFORMITY

Replaces version dated:
24.01.2020
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 products are in conformity with Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Classification:
Category I according to the **Regulation (EU) 2016/425 on personal protective equipment**

List of devices:

REF	Product name
210415	**SELEFA® Apron Notos, white, embossed**
21043050	**SELEFA® Apron Bosco, transparent, embossed**
210433	**SELEFA® Apron Divina, transparent, in roll, embossed**
210434	**SELEFA® Apron Emmy, transparent, embossed**
210435	**SELEFA® Apron Felix, transparent, extra long, in roll, embossed**
210445	**SELEFA® Apron Bosco Green, transparent, embossed**
3210446	**Embra® Apron Bosco Green, transparent, embossed**

These items are in conformity with following European standards and common specifications[1]:

EN ISO 15223-1 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements

[1]Relevant standards, latest applied revisions and common specifications are listed in *T-079 Review of regulations and standards*

The product(s) is (are) subject to conformity assessment procedure Module A, internal production control, according to Annex IV, Regulation (EU) 2016/425.

Place and date of issue Helsinki 15.12.2023

Name and signature of the authorized person

Hilleriikka Vaho
Regulatory Manager
OneMed Group Oy