

## EU DECLARATION OF CONFORMITY

Replaces version dated:  
15.12.2023  
Valid until the issue of next version  
of this document.

We,

**OneMed Group Oy,**  
Metsäläntie 20,  
FI-00320 Helsinki, Finland,

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:

Item number (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, green, embossed
3210446	Embra® Apron BOSCO, transparent, embossed
100011	Embra® Apron EMMY, transparent, embossed

These items are in conformity with following European standards and common specifications<sup>1</sup>:

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

<sup>1</sup>Relevant standards and latest applied revisions are listed in *GEN-079 Review of regulation 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 29.01.2025

Name and signature of the authorized person



Hilleriikka Vaho  
Regulatory Affairs Manager  
OneMed Group Oy

For Reference Only