

EU DECLARATION OF CONFORMITY

Replaces version dated:
21.04.2022
Valid until the issue of next version
of this document.

We,
OneMed Group Oy, Domicile Helsinki,
Metsäläntie 20, Business ID 20399640-1,
FI-00320 Helsinki, Finland,

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
211552	SELEFA® Shoe Cover, 15 x 45 cm, blue
211553	SELEFA® Shoe Cover, 15 x 40 cm, white
211554	SELEFA® Shoe Cover, 15 x 41 cm, blue
211555	SELEFA® Shoe Cover, 15 x 45 cm, blue
3211554	Embra® Shoe Cover, 15 x 41 cm, green
3211555	Embra® Shoe Cover, 15 x 45 cm, green

These items are in conformity with following European standards and common specifications¹:

EN ISO 15223-1

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

¹Relevant standards and latest applied revisions are listed in *T-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 11.09.2023

Name and signature of the authorized person


Hillerikka Vaho
Regulatory Manager
OneMed Group Oy