

EU DECLARATION OF CONFORMITY

replaces version dated: 09.12.2021

We

OneMed Group Oy, Metsäläntie 20, FI-00320 Helsinki

declare under our sole responsibility as manufacturer that following CE marked products, all belonging to category I according to Annex I of the Regulation (EU) 2016/425 on personal protective equipment,

Item number (REF)	Trade and product name
211550	SELEFA® Shoe Cover, 15 x 40 cm, white
211551	SELEFA® Shoe Cover, 15 x 41 cm, blue
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

to which this declaration relates, are in conformity with Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment, and fulfills applicable Essential health and safety requirements set out in Annex II, Regulation (EU) 2016/425. The product(s) comply with the following standards and specifications¹:

EN ISO 1041	Information supplied by the manufacturer of medical devices
EN ISO 15223-1	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements

¹Latest applied revisions of regulations, standards and common specifications 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

Göteborg 21.04.2022

Name and signature



Martin Hillbratt

Quality and Regulatory Director
OneMed Group Oy