Declaration of conformity for medical device

Our company,

Ofa Bamberg GmbH Laubanger 20 D - 96052 Bamberg

declares hereby as responsible manufacturer and under sole responsibility that the medical devices listed in Annex comply with all relevant requirements of Regulation (EU) 2017/745 (MDR) in its current consolidated form.

A notified body is not involved in the conformity assessment procedure.

Classification:

1

(according to Annex VIII, Rule 1)

Single Registration Number (SRN):

DE-MF-000008470

Basic-UDI-DI:

4018839K039L

Conformity assessment:

according to Article 52 & Annex II - IV

CE- labelling:

СE

Validity of the declaration of conformity:

February 28, 2029

Intended purpose:

Compression stockings for the prophylaxis of vein problems.

The validity of this declaration of conformity ends with a new declaration of conformity.

Ofa Bamberg GmbH Bamberg, 01.03.2024

Rainer Kliewe

Managing director

Dr. Fabian Bohnen

Person responsible for regulatory compliance

according to article 15, MDR

Annex

Product	REF-number (14. or 16. digit)
Belsana® Medical Cotton	2310
Belsana® Medical Mikrofaser	2315
Belsana® Medical Aloe Vera	2316
Belsana® Traveller	2317
Belsana® Work Skincare	2335
Belsana® Work	2339
Belsana® Traveller Woman	2339
Belsana® Prenatal	2339