Declaration of conformity for accessories of a medical device

Our company,

Ofa Bamberg GmbH Laubanger 20 D - 96052 Bamberg

declares hereby as responsible manufacturer and under sole responsibility that the accessories of a medical device 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:

accessory of a medical device class I

(according to Annex VIII, Rule 1)

Single Registration Number (SRN):

DE-MF-000008470

Basic-UDI-DI:

4018839Z01BT

Conformity assessment:

according to Article 52 & Annex II - IV

CE- labelling:

CE

Validity of the declaration of conformity:

February 28, 2029

Intended purpose:

Makes it easier to put on support and compression stockings.

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

accessory	REF-number (14. or 16. digit)
Belsana® angel	299809
Belsana® angel big	299808