

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: I
(according to Annex VIII, Rule 1)
Single Registration Number (SRN): DE-MF-000008470
Basic-UDI-DI: 4018839K029J
Conformity assessment: according to Article 52 & Annex II - IV
CE- labelling: CE
Validity of the declaration of conformity: February 28, 2029
Intended purpose:

Medical compression stockings for the treatment of lymphological diseases, lipedema and scar therapy.

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 (1.-4. or 1.-6. digit)
Belsana® Classic Extra CCL I	2224
Belsana® Impuls CCL I	2225
Belsana® Classic Extra CCL II	2244
Belsana® Impuls CCL II	2245
Belsana® Classic Extra CCL III	2264
Belsana® Impuls CCL III	2265
Belsana® Classic Extra CCL IV	2274
Belsana® Impuls CCL IV	2275
Belsana® Impuls CCL II	2745
Belsana® Impuls CCL III	2765