

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:	4018839K019G
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 phlebological diseases.

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 with cotton CCL II	2134
Belsana® Classic with cotton CCL III	2135
Belsana® Comfortis CCL I	2151
Belsana® Classic CCL I	2152
Belsana® Comfortis CCL II	2153
Belsana® Classic CCL II	2154
Belsana® Evo®lution CCL II	2158
Belsana® Vivere CCL II	2180
Belsana® Microsoft CCL I	2181
Belsana® Microsoft CCL II	2182
Belsana® Power CCL I	2185
Belsana® Power CCL II	2186
Belsana® Classic with cotton CCL II	2234
Belsana® Classic with cotton CCL III	2235
Belsana® Comfortis CCL I	2251
Belsana® Classic CCL I	2252
Belsana® Comfortis CCL II	2253
Belsana® Classic CCL II	2254
Belsana® Vivere CCL II	2280
Belsana® Microsoft CCL I	2281
Belsana® Microsoft CCL II	2282
Belsana® Power CCL I	2285
Belsana® Power CCL II	2286