

BSN-JOBST GmbH Declaration of Conformity

Valid from:
date of last signature
Page 1 of 1

We,

BSN-JOBST GmbH
Beiersdorfstraße 1
46446 Emmerich am Rhein
Germany
(SRN: not issued yet)

hereby declare under our own responsibility, that this product family complies with the applicable regulations of the regulation (EU) 2017/745 of the European parliament and of the council on medical devices (MDR).

Product name: **JOBST UltraSheer CCL1 Lower RTW**

Basic UDI-DI: 40197024004388283

Intended purpose: The intended use of the BSN-JOBST Circular knitted compression garments is the external, physical compression for the management of venous (chronic / acute) and lymphatic diseases and lipedema of lower and upper extremities. They are indicated for the management of oedema/swelling of different origins.

Conformity assessment route: Annex II + III

Classification rule: 4

Classification: I

The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485 and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.


Compiled and released:
Emmerich am Rhein,
Ulrike Sonntag
Quality & Regulatory Affairs Manager
BSN-JOBST GmbH

Doc.-no.: DoC-LO-US-1-RTW

Version 02