

We,

**BSN medical GmbH
Quickbornstr. 24
20253 Hamburg
Germany
(SRN: DE-MF-000005787)**

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

Product Name:

Elastomull®

Basic UDI-DI:

4042809400355649D

Intended purpose:

Elastomull® is intended for fixation of wound dressings on all parts of the body and on joints.

Conformity assessment route: **Annex II+III**

Classification rule: **1**

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.

Date of Issue: 21.04.2020

Compiled and released:

Hamburg, 21.04.2020
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
02094-00000-03	ELASTOMULL WRAP AROUND 4CMX4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV 20/BOX	02094-00
02095-00000-05	ELASTOMULL WRAP AROUND 6CMX4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV 20/BOX	02095-00
02096-00000-05	ELASTOMULL WRAP AROUND 8CMX4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV 20/BOX	02096-00
02097-00000-05	ELASTOMULL WRAP AROUND 10CMX4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV 20/BOX	02097-00
02098-00000-05	ELASTOMULL WRAP AROUND 12CMX4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV 20/BOX	02098-00
02099-00000-03	ELASTOMULL 4CMX4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV 20/BOX	02099-00
02100-00000-03	ELASTOMULL 6CMX4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV 20/BOX	02100-00
02101-00000-03	ELASTOMULL 8CMX4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV 20/BOX	02101-00
02102-00000-03	ELASTOMULL 10CMX4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV 20/BOX	02102-00
02103-00000-03	ELASTOMULL 12CMX4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV 20/BOX	02103-00
45250-00000-03	ELASTOMULL 4CMX4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV 50/BOX	45250-00
45251-00000-03	ELASTOMULL 6CMX4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV 100/BOX	45251-00
45252-00000-03	ELASTOMULL 8CMX4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV 100/BOX	45252-00
45253-00000-03	ELASTOMULL 10CMX4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV 50/BOX	45253-00
79996-00001-03	LEUKOPLAST ELASTOMULL 8CMX4M WHITE 2 NL FR DE IT AT CH FR NL	79996-01
79996-00002-03	LEUKOPLAST ELASTOMULL 10CMX4M WHITE 2 NL FR DE IT AT CH FR NL	79996-02
79996-00004-02	LEUKOPLAST ELASTOMULL 8CMX4M WHITE 2	79996-04

Article	Description	REF
	IT PT ES	
79996-00005-02	LEUKOPLAST ELASTOMULL 10CMX4M WHITE 2 IT PT ES	79996-05
79996-00007-02	LEUKOPLAST ELASTOMULL 8CM X 4M WHITE 2 DA EN FI NO SV NORDIC	79996-07
79996-00008-02	LEUKOPLAST ELASTOMULL 10CMX4M WHITE 2 DA EN FI NO SV NORDIC	79996-08