

We,

BSN medical GmbH
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(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:

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Classification:

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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.

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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 |