

We,

**BSN medical GmbH
Schützenstr. 1-3
22761 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® haft / Elastomull® haft hospital

Basic UDI-DI:

4042809400355399E

Intended purpose:

Elastomull® haft / Elastomull® haft hospital is intended for fixation of wound dressings of all types and sizes as well as devices such as splints, tubes and paddings, for short term application of compression and to provide general support.

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.

Date of Issue: 07.03.2023

Compiled and released:

Hamburg, 07.03.2023
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
45470-00000-05	ELASTOMULL HAFT LATEX FREE 4CMX4M WHITE 1 NL EN FR DE EL IT PT SV	45470-00
45470-00001-05	ELASTOMULL HAFT LATEX FREE 4CMX4M WHITE 1 IT MUTUA 45470-00-05	45470-01
45470-00002-05	ELASTOMULL HAFT LATEX FREE 4CMX4M WHITE 1 FR LPPR 45470-00-05	45470-02
45471-00000-07	ELASTOMULL HAFT LATEX FREE 6CMX4M WHITE 1 NL EN FR DE EL IT PT SV	45471-00
45471-00001-07	ELASTOMULL HAFT LATEX FREE 6CMX4M WHITE 1 IT MUTUA 45471-00-07	45471-01
45471-00002-07	ELASTOMULL HAFT LATEX FREE 6CMX4M WHITE 1 FR LPPR 45471-00-07	45471-02
45472-00000-07	ELASTOMULL HAFT LATEX FREE 8CMX4M WHITE 1 NL EN FR DE EL IT PT SV	45472-00
45472-00001-07	ELASTOMULL HAFT LATEX FREE 8CMX4M WHITE 1 IT MUTUA 45472-00-07	45472-01
45472-00002-07	ELASTOMULL HAFT LATEX FREE 8CMX4M WHITE 1 FR LPPR 45472-00-07	45472-02
45473-00000-07	ELASTOMULL HAFT LATEX FREE 10CMX4M WHITE 1 NL EN FR DE EL IT PT SV	45473-00
45473-00001-07	ELASTOMULL HAFT LATEX FREE 10CMX4M WHITE 1 IT MUTUA 45473-00-07	45473-01
45473-00002-07	ELASTOMULL HAFT LATEX FREE 10CMX4M WHITE 1 FR LPPR 45473-00-07	45473-02
45474-00000-07	ELASTOMULL HAFT LATEX FREE 12CMX4M WHITE 1 NL EN FR DE EL IT PT SV	45474-00
45474-00001-07	ELASTOMULL HAFT LATEX FREE 12CMX4M WHITE 1 IT MUTUA 45474-00-07	45474-01
45474-00002-07	ELASTOMULL HAFT LATEX FREE 12CMX4M WHITE 1 FR LPPR 45474-00-07	45474-02
45475-00000-06	ELASTOMULL HAFT LATEX FREE 4CMX20M WHITE 1 NL EN FR DE EL IT PT SV	45475-00
45475-00001-06	ELASTOMULL HAFT LATEX FREE 4CMX20M WHITE 1 IT MUTUA 45475-00-06	45475-01
45476-00000-07	ELASTOMULL HAFT LATEX FREE 6CMX20M WHITE 1 NL EN FR DE EL IT PT SV	45476-00
45476-00001-07	ELASTOMULL HAFT LATEX FREE 6CMX20M	45476-01

Article	Description	REF
	WHITE 1 IT MUTUA 45476-00-07	
45477-00000-06	ELASTOMULL HAFT LATEX FREE 8CMX20M WHITE 1 NL EN FR DE EL IT PT SV	45477-00
45477-00001-06	ELASTOMULL HAFT LATEX FREE 8CMX20M WHITE 1 IT MUTUA 45477-00-06	45477-01
45478-00000-06	ELASTOMULL HAFT LATEX FREE 10CMX20M WHITE 1 NL EN FR DE EL IT PT SV	45478-00
45478-00001-06	ELASTOMULL HAFT LATEX FREE 10CMX20M WHITE 1 IT MUTUA 45478-00-06	45478-01
45479-00000-06	ELASTOMULL HAFT LATEX FREE 12CMX20M WHITE 1 NL EN FR DE EL IT PT SV	45479-00
45479-00001-06	ELASTOMULL HAFT LATEX FREE 12CMX20M WHITE 1 IT MUTUA 45479-00-06	45479-01
47246-00000-04	ELASTOMULL HAFT LATEX FREE 6CMX20M WHITE 1 NL EN FR DE EL IT PT ES SV 6/BOX	47246-00
47249-00000-04	ELASTOMULL HAFT LATEX FREE 8CMX20M WHITE 1 NL EN FR DE EL IT PT ES SV 6/BOX	47249-00
47303-00000-04	ELASTOMULL HAFT LATEX FREE 10CMX20M WHITE 1 NL EN FR DE EL IT PT ES SV 6/BOX	47303-00
71215-00000-01	LEUKOPLAST ELASTOMULL HAFT LATEX FREE 12CMX4M WHITE 1 IT PT ES	71215-00
71215-00001-01	LEUKOPLAST ELASTOMULL HAFT LATEX FREE 6CMX4M WHITE 1 IT PT ES	71215-01
71215-00002-01	LEUKOPLAST ELASTOMULL HAFT LATEX FREE 4CMX4M WHITE 1 IT PT ES	71215-02
71215-00003-01	LEUKOPLAST ELASTOMULL HAFT LATEX FREE 4CMX4M WHITE 1 DA EN FI NO SV NORDIC	71215-03
76194-00000-03	ELASTOMULL HAFT HOSPITAL LATEX FREE 4CMX20M WHITE 1 DA NL EN FI FR DE ID IT NO ES SV	76194-00
76194-00001-03	ELASTOMULL HAFT HOSPITAL LATEX FREE 6CMX20M WHITE 1 DA NL EN FI FR DE ID IT NO ES SV	76194-01
76194-00002-03	ELASTOMULL HAFT HOSPITAL LATEX FREE 8CMX20M WHITE 1 DA NL EN FI FR DE ID IT NO ES SV	76194-02
76194-00003-03	ELASTOMULL HAFT HOSPITAL LATEX FREE	76194-03

Article	Description	REF
	10CMX20M WHITE 1 DA NL EN FI FR DE ID IT NO ES SV	
76194-00004-03	ELASTOMULL HAFT HOSPITAL LATEX FREE 12CMX20M WHITE 1 DA NL EN FI FR DE ID IT NO ES SV	76194-04
76194-00005-03	ELASTOMULL HAFT HOSPITAL LATEX FREE 6CMX20M WHITE 1 DA NL EN FI FR DE ID IT NO ES SV 6/BOX	76194-05
76194-00006-03	ELASTOMULL HAFT HOSPITAL LATEX FREE 8CMX20M WHITE 1 DA NL EN FI FR DE ID IT NO ES SV 6/BOX	76194-06
76194-00007-03	ELASTOMULL HAFT HOSPITAL LATEX FREE 10CMX20M WHITE 1 DA NL EN FI FR DE ID IT NO ES SV 6/BOX	76194-07
79997-00001-04	LEUKOPLAST ELASTOMULL HAFT 8CMX4M WHITE 1 NL FR DE IT AT CH FR NL	79997-01
79997-00002-04	LEUKOPLAST ELASTOMULL HAFT 10CMX4M WHITE 1 NL FR DE IT AT CH FR NL	79997-02
79997-00003-03	LEUKOPLAST ELASTOMULL HAFT 8CMX4M WHITE 1 IT PT ES	79997-03
79997-00004-03	LEUKOPLAST ELASTOMULL HAFT 10CMX4M WHITE 1 IT PT ES	79997-04
79997-00005-03	LEUKOPLAST ELASTOMULL HAFT 8CMX4M WHITE 1 DA EN FI NO SV NORDIC	79997-05
79997-00006-03	LEUKOPLAST ELASTOMULL HAFT 10CMX4M WHITE 1 DA EN FI NO SV NORDIC	79997-06