

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:

Fixomull®/Hypafix® skin sensitive

Basic UDI-DI:

4042809400329308T

Intended purpose:

Fixomull®/Hypafix® skin sensitive is intended for fixation of primary wound dressings and additional securement of devices, such as catheters, tubes, probes or drainages.

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.

Declaration of conformity issued: 05.02.2025

Compiled and released:

Hamburg, 05.02.2025
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
79965-00001-04	FIXOMULL SKIN SENSITIVE 5CMX5M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	79965-01
79965-00002-04	FIXOMULL SKIN SENSITIVE 10CMX5M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	79965-02
79965-00003-04	FIXOMULL SKIN SENSITIVE 15CMX5M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	79965-03
79965-00004-04	FIXOMULL SKIN SENSITIVE 10CMX2M WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	79965-04
79966-00001-04	HYPAFIX SKIN SENSITIVE 5CMX5M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	79966-01
79966-00002-04	HYPAFIX SKIN SENSITIVE 10CMX5M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	79966-02
79966-00003-02	HYPAFIX SKIN SENSITIVE 15CMX5M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	79966-03
79966-00004-04	HYPAFIX SKIN SENSITIVE 10CMX2M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	79966-04