

We,

**BSN medical GmbH
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22761 Hamburg
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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:

Fixomull®/Hypafix® transparent

Basic UDI-DI:

4042809400329318V

Intended purpose:

Fixomull® / Hypafix® transparent is indicated for wide area fixation of wound dressings, tubes, catheters, instruments and measuring devices.

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.

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Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
72216-00000-04	FIXOMULL TRANSPARENT 5CMX10M 1 DA NL EN FI FR DE IT PT ES SV	72216-00
72216-00001-04	FIXOMULL TRANSPARENT 10CMX10M 1 DA NL EN FI FR DE IT PT ES SV	72216-01
72216-00002-04	FIXOMULL TRANSPARENT 15CMX10M 1 DA NL EN FI FR DE IT PT ES SV	72216-02
72217-00000-04	FIXOMULL TRANSPARENT 10CMX2M 1 DA NL EN FI FR DE IT PT ES SV	72217-00
72217-00001-04	FIXOMULL TRANSPARENT 10CMX2M 1 DA NL EN FI FR DE IT PT ES SV	72217-01
72217-00002-04	FIXOMULL TRANSPARENT 10CMX2M 1 DA NL EN FI FR DE IT PT ES SV	72217-02
72378-00000-05	HYPAFIX TRANSPARENT 5CMX10M 1 EN FR ES DE	72378-00
72378-00001-05	HYPAFIX TRANSPARENT 10CMX10M 1 EN FR ES DE	72378-01
72378-00002-05	HYPAFIX TRANSPARENT 15CMX10M 1 EN FR ES DE	72378-02
72378-00003-05	HYPAFIX TRANSPARENT 10CMX2M 1 EN FR ES DE	72378-03
72378-00004-05	HYPAFIX TRANSPARENT 10CMX2M 1 FR 72378-3-5 LPPR	72378-04
72378-00005-05	HYPAFIX TRANSPARENT 5CMX10M 1 FR LPPR 72378-0-5	72378-05
72378-00006-05	HYPAFIX TRANSPARENT 10CMX10M 1 FR LPPR 72378-1-5	72378-06
72378-00007-05	HYPAFIX TRANSPARENT 15CMX10M 1 FR LPPR 72378-2-5	72378-07