

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®

Basic UDI-DI: 40428094003292796

Fixomull® is intended for wide-area fixation of wound Intended purpose:

dressings, particularly for the fixation of large wound dressings on less contoured parts of the body.

To exert compression or relieve tension. Fixation of tubes,

probes, catheters, measuring devices, instruments. Support for the treatment of club foot.

Conformity assessment route: Annex II+III

Classification rule:

Classification:

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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Hamburg, 21.09.2023 Martin Spengler Director Regulatory Affairs Hamburg

BSN medicăl GmbH

Hadir Mula



Declaration of Conformity Fixomull®

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Article	Description	REF
02110-00001-05	FIXOMULL 10CMX10M 1 DE EN FR EL IT	02110-01
02110-00002-05	FIXOMULL 10CMX10M 1 FR LPPR 02110-1-5	02110-02
02111-00001-05	FIXOMULL 15CMX10M 1 FR EL IT EN DE	02111-01
02111-00002-05	FIXOMULL 15CMX10M 1 FR LPPR 02111-1-5	02111-02