

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® stretch

Basic UDI-DI:

4042809400325658S

Intended purpose:

Fixomull® stretch is intended for wide area fixation of wound dressings, particularly on joints as well as on frequently moved and contoured parts of the body. The product can also be used to secure fixation of tubes, catheters, measuring devices and instruments and can be used for one day to several days depending on the status of the wound and on the skin condition.

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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Compiled and released:

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Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
02033-00000-09	FIXOMULL STRETCH 15CMX2M WHITE 1 FR NL DE	02033-00
02033-00001-09	FIXOMULL STRETCH 15CMX2M WHITE 1 EN IT PT ES	02033-01
02036-00000-11	FIXOMULL STRETCH 5CMX10M WHITE 1 IT DE FR EN EL	02036-00
02037-00000-11	FIXOMULL STRETCH 10CMX10M WHITE 1 FR DE EN IT EL	02037-00
02038-00000-11	FIXOMULL STRETCH 15CMX10M WHITE 1 FR EN DE IT EL	02038-00
02039-00000-11	FIXOMULL STRETCH 20CMX10M WHITE 1 IT EL FR EN DE	02039-00
02040-00000-11	FIXOMULL STRETCH 30CMX10M WHITE 1 EL IT FR EN DE	02040-00
09084-00000-05	FIXOMULL STRETCH 5CMX10M WHITE 1 DE	09084-00
09085-00000-05	FIXOMULL STRETCH 10CMX10M WHITE 1 DE	09085-00
09086-00000-05	FIXOMULL STRETCH 15CMX10M WHITE 1 DE	09086-00
09087-00000-05	FIXOMULL STRETCH 20CMX10M WHITE 1 DE	09087-00
09088-00000-05	FIXOMULL STRETCH 30CMX10M WHITE 1 DE	09088-00
47272-00000-07	FIXOMULL STRETCH 5CMX5M WHITE 1 IT DE W.O.SPLIT	47272-00
47375-00000-06	FIXOMULL STRETCH 10CMX20M WHITE 1 EN DE IT EL FR W.O.SPLIT	47375-00
47376-00000-06	FIXOMULL STRETCH 15CMX20M WHITE 1 FR EN DE EL IT W.O.SPLIT	47376-00
47377-00000-06	FIXOMULL STRETCH 20CMX20M WHITE 1 DE EN FR IT EL W.O.SPLIT	47377-00
70022-00000-05	FIXOMULL STRETCH 10CMX2M WHITE 1 NL FR DE	70022-00
70022-00001-05	FIXOMULL STRETCH 10CMX2M WHITE 1 EN IT PT	70022-01
70022-00003-05	FIXOMULL STRETCH 10CMX2M WHITE 1 DA FI NO SV	70022-03
71216-00000-02	FIXOMULL STRETCH 10CMX1M WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	71216-00
71217-00000-02	LEUKOPLAST FIXOMULL STRETCH 15CMX10M	71217-00

Article	Description	REF
	WHITE 1 IT PT ES	
71217-00001-02	LEUKOPLAST FIXOMULL STRETCH 10CMX2M WHITE 1 IT PT ES	71217-01
71217-00002-02	LEUKOPLAST FIXOMULL STRETCH 15CMX2M WHITE 1 IT PT ES	71217-02
72592-00000-03	FIXOMULL STRETCH 5CMX20M WHITE 1 DE	72592-00
72592-00001-03	FIXOMULL STRETCH 10CMX20M WHITE 1 DE	72592-01
72592-00002-03	FIXOMULL STRETCH 15CMX20M WHITE 1 DE	72592-02
72592-00003-03	FIXOMULL STRETCH 20CMX20M WHITE 1 DE	72592-03
72592-00004-03	FIXOMULL STRETCH 30CMX20M WHITE 1 DE	72592-04
76991-00001-05	FIXOMULL STRETCH 15CMX5M WHITE 1 ID	76991-01
76992-00001-05	FIXOMULL STRETCH 10CMX5M WHITE 1 ID	76992-01
76993-00001-05	FIXOMULL STRETCH 5CMX5M WHITE 1 ID	76993-01
79992-00000-05	LEUKOPLAST FIXOMULL STRETCH 5CMX10M WHITE 1 NL FR DE IT AT CH FR NL	79992-00
79992-00001-04	LEUKOPLAST FIXOMULL STRETCH 5CMX10M WHITE 1 IT PT ES	79992-01
79992-00002-05	LEUKOPLAST FIXOMULL STRETCH 10CMX10M WHITE 1 NL FR DE IT AT CH FR NL	79992-02
79992-00003-04	LEUKOPLAST FIXOMULL STRETCH 10CMX10M WHITE 1 IT PT ES	79992-03
79992-00004-04	LEUKOPLAST FIXOMULL STRETCH 5CMX5M WHITE 1 IT PT ES	79992-04
79992-00005-05	LEUKOPLAST FIXOMULL STRETCH 10CMX2M WHITE 1 NL FR DE IT AT CH FR NL	79992-05
79992-00006-04	LEUKOPLAST FIXOMULL STRETCH 5CMX10M WHITE 1 DA EN FI NO SV NORDIC	79992-06
79992-00007-04	LEUKOPLAST FIXOMULL STRETCH 10CMX10M WHITE 1 DA EN FI NO SV NORDIC	79992-07
79992-00008-04	LEUKOPLAST FIXOMULL STRETCH 10CMX2M WHITE 1 DA EN FI NO SV NORDIC	79992-08