

We,

**BSN medical GmbH  
Schützenstr. 1-3  
22761 Hamburg  
Germany  
(SRN: DE-MF-000005787)**

hereby declare under our own responsibility, that this product family complies with the applicable regulations 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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Hamburg, 02.12.2021  
Martin Spengler  
Director Regulatory Affairs Hamburg  
BSN medical GmbH



| Article        | Description   | REF      |
|----------------|---|----------|
| 02033-00000-08 | FIXOMULL STRETCH 15CMX2M WHITE 1 FR NL DE                         | 02033-00 |
| 02033-00001-08 | FIXOMULL STRETCH 15CMX2M WHITE 1 EN IT PT ES                      | 02033-01 |
| 02036-00000-10 | FIXOMULL STRETCH 5CMX10M WHITE 1 IT DE FR EN EL                   | 02036-00 |
| 02037-00000-10 | FIXOMULL STRETCH 10CMX10M WHITE 1 FR DE EN IT EL                  | 02037-00 |
| 02038-00000-10 | FIXOMULL STRETCH 15CMX10M WHITE 1 FR EN DE IT EL                  | 02038-00 |
| 02039-00000-10 | FIXOMULL STRETCH 20CMX10M WHITE 1 IT EL FR EN DE                  | 02039-00 |
| 02040-00000-10 | FIXOMULL STRETCH 30CMX10M WHITE 1 EL IT FR EN DE                  | 02040-00 |
| 09084-00000-04 | FIXOMULL STRETCH 5CMX10M WHITE 1 DE                               | 09084-00 |
| 09085-00000-04 | FIXOMULL STRETCH 10CMX10M WHITE 1 DE                              | 09085-00 |
| 09086-00000-04 | FIXOMULL STRETCH 15CMX10M WHITE 1 DE                              | 09086-00 |
| 09087-00000-04 | FIXOMULL STRETCH 20CMX10M WHITE 1 DE                              | 09087-00 |
| 09088-00000-04 | FIXOMULL STRETCH 30CMX10M WHITE 1 DE                              | 09088-00 |
| 47272-00000-06 | FIXOMULL STRETCH 5CMX5M WHITE 1 IT DE W.O.SPLIT                   | 47272-00 |
| 47375-00000-05 | FIXOMULL STRETCH 10CMX20M WHITE 1 EN DE IT EL FR W.O.SPLIT        | 47375-00 |
| 47376-00000-05 | FIXOMULL STRETCH 15CMX20M WHITE 1 FR EN DE EL IT W.O.SPLIT        | 47376-00 |
| 47377-00000-05 | FIXOMULL STRETCH 20CMX20M WHITE 1 DE EN FR IT EL W.O.SPLIT        | 47377-00 |
| 70022-00000-04 | FIXOMULL STRETCH 10CMX2M WHITE 1 NL FR DE                         | 70022-00 |
| 70022-00001-04 | FIXOMULL STRETCH 10CMX2M WHITE 1 EN IT PT                         | 70022-01 |
| 70022-00003-04 | FIXOMULL STRETCH 10CMX2M WHITE 1 DA FI NO SV                      | 70022-03 |
| 71216-00000-01 | FIXOMULL STRETCH 10CMX1M WHITE 1 DA NL EN FI FR DE IT NO PT ES SV | 71216-00 |
| 71217-00000-01 | LEUKOPLAST FIXOMULL STRETCH 15CMX10M                              | 71217-00 |

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