

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® 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.

Declaration of conformity issued: 23.02.2024

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Compiled and released:

Hamburg, 23.02.2024  
Martin Spengler  
Director Regulatory Affairs Hamburg  
BSN medical GmbH



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