

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:

**Gazofix® / Gazofix® color**

Basic UDI-DI:

**4042809400327959D**

Intended purpose:

**Gazofix® / Gazofix® color (latexfree) is intended for fixation of wound dressings of all types and sizes as well as devices such as splints, tubes and paddings, for short term application of compression and to provide general support.**

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.

Date of Issue: 12.04.2023

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Compiled and released:

Hamburg, 12.04.2023  
Martin Spengler  
Director Regulatory Affairs Hamburg  
BSN medical GmbH



| Article        | Description                                                                    | REF      |
|----------------|--------------------------------------------------------------------------------|----------|
| 02935-00001-02 | GAZOFIX LATEX FREE 4CMX4M TAN 1 DE DA<br>EN FI FR IT NL NO PT SV ES            | 02935-01 |
| 02936-00001-02 | GAZOFIX LATEX FREE 6CMX4M TAN 1 DE DA<br>EN FI FR IT NL NO PT SV ES            | 02936-01 |
| 02937-00001-02 | GAZOFIX LATEX FREE 8CMX4M TAN 1 DE DA<br>EN FI FR IT NL NO PT SV ES            | 02937-01 |
| 02938-00001-02 | GAZOFIX LATEX FREE 10CMX4M TAN 1 DE DA<br>EN FI FR IT NL NO PT SV ES           | 02938-01 |
| 02939-00001-02 | GAZOFIX LATEX FREE 12CMX4M TAN 1 DE DA<br>EN FI FR IT NL NO PT SV ES           | 02939-01 |
| 46640-00001-02 | GAZOFIX LATEX FREE 4CMX20M TAN 1 EL IT<br>NO NL PT SV DE DA EN FI FR           | 46640-01 |
| 46641-00001-02 | GAZOFIX LATEX FREE 6CMX20M TAN 1 EL IT<br>NO NL PT SV DE DA EN FI FR           | 46641-01 |
| 46642-00001-02 | GAZOFIX LATEX FREE 8CMX20M TAN 1 EL IT<br>NO NL PT SV DE DA EN FI FR           | 46642-01 |
| 46643-00001-02 | GAZOFIX LATEX FREE 10CMX20M TAN 1 EL IT<br>NO NL PT SV DE DA EN FI FR          | 46643-01 |
| 46644-00001-02 | GAZOFIX LATEX FREE 12CMX20M TAN 1 EL IT<br>NO NL PT SV DE DA EN FI FR          | 46644-01 |
| 47328-00001-02 | GAZOFIX COLOR LATEX FREE 6CMX20M BLUE<br>1 DA NL EN FI FR DE EL IT NO PT ES SV | 47328-01 |
| 47329-00001-02 | GAZOFIX COLOR LATEX FREE 8CMX20M BLUE<br>1 DA NL EN FI FR DE EL IT NO PT       | 47329-01 |
| 47331-00001-02 | GAZOFIX COLOR LATEX FREE 6CMX20M<br>YELLOW 1 FI FR EN DA DE SE PT NL NO IT EL  | 47331-01 |
| 47332-00001-02 | GAZOFIX COLOR LATEX FREE 8CMX20M<br>YELLOW 1 FI FR EN DA DE SE PT NL NO IT EL  | 47332-01 |
| 47334-00001-02 | GAZOFIX COLOR LATEX FREE 6CMX20M<br>GREEN 1 DA NL EN FI FR DE EL IT NO PT SV   | 47334-01 |
| 47335-00001-02 | GAZOFIX COLOR LATEX FREE 8CMX20M<br>GREEN 1 DA NL EN FI FR DE EL IT NO PT SV   | 47335-01 |
| 47337-00001-02 | GAZOFIX COLOR LATEX FREE 6CMX20M PINK<br>1 DA NL EN FI FR DE EL IT PT SV       | 47337-01 |
| 47338-00001-02 | GAZOFIX COLOR LATEX FREE 8CMX20M PINK<br>1 DA NL EN FI FR DE EL IT PT SV       | 47338-01 |
| 76047-00001-02 | GAZOFIX COLOR LATEX FREE 6CMX20M BLUE                                          | 76047-01 |

| Article        | Description                                                                            | REF      |
|----------------|----------------------------------------------------------------------------------------|----------|
|                | 1 EL IT NO NL PT DE DA 6/BOX                                                           |          |
| 76048-00001-02 | GAZOFIX COLOR LATEX FREE 8CMX20M BLUE<br>1 EL IT NO NL PT DE DA 6/BOX                  | 76048-01 |
| 76049-00001-02 | GAZOFIX COLOR LATEX FREE 6CMX20M<br>YELLOW 1 DA NL EN FI FR DE EL IT NO PT<br>6/BOX    | 76049-01 |
| 76050-00001-02 | GAZOFIX COLOR LATEX FREE 8CMX20M<br>YELLOW 1 DA NL EN FI FR DE EL IT NO PT SV<br>6/BOX | 76050-01 |
| 76051-00001-02 | GAZOFIX COLOR LATEX FREE 6CMX20M PINK<br>1 DA NL EN FI FR DE EL IT NO PT SV 6/BOX      | 76051-01 |
| 76052-00001-02 | GAZOFIX COLOR LATEX FREE 8CMX20M PINK<br>1 DA NL EN FI FR DE EL IT NO PT SV 6/BOX      | 76052-01 |
| 79993-00000-02 | GAZOFIX COLOR LATEX FREE 6CMX20M<br>GREEN 1 EL IT NO NL PT DE DA 6/BOX                 | 79993-00 |
| 79993-00001-02 | GAZOFIX COLOR LATEX FREE 8CMX20M<br>GREEN 1 EL IT NO NL PT DE DA 6/BOX                 | 79993-01 |