

We,

**BSN medical GmbH
Quickbornstrasse 24
20253 Hamburg
Germany
(SRN: NOT ISSUED YET)**

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: **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: 29.04.2020

Compiled and released:

Hamburg, 29.04.2020
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Declaration of Conformity
Gazofix® / Gazofix®
color

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

Declaration of Conformity
Gazofix® / Gazofix®
color

Article	Description	REF
	SV	
47338-00001-01	GAZOFIX COLOR LATEX FREE LATEX FREE 8CMX20M PINK 1 DA NL EN FI FR DE EL IT PT SV	47338-01
76047-00001-01	GAZOFIX COLOR LATEX FREE 6CMX20M BLUE 1 EL IT NO NL PT DE DA 6/BOX	76047-01
76048-00001-01	GAZOFIX COLOR LATEX FREE 8CMX20M BLUE 1 EL IT NO NL PT DE DA 6/BOX	76048-01
76049-00001-01	GAZOFIX COLOR LATEX FREE 6CMX20M YELLOW 1 DA NL EN FI FR DE EL IT NO PT 6/BOX	76049-01
76050-00001-01	GAZOFIX COLOR LATEX FREE 8CMX20M YELLOW 1 DA NL EN FI FR DE EL IT NO PT SV 6/BOX	76050-01
76051-00001-01	GAZOFIX COLOR LATEX FREE 6CMX20M PINK 1 DA NL EN FI FR DE EL IT NO PT SV 6/BOX	76051-01
76052-00001-01	GAZOFIX COLOR LATEX FREE 8CMX20M PINK 1 DA NL EN FI FR DE EL IT NO PT SV 6/BOX	76052-01
79993-00000-01	GAZOFIX COLOR LATEX FREE 6CMX20M GREEN 1 EL IT NO NL PT DE DA 6/BOX	79993-00
79993-00001-01	GAZOFIX COLOR LATEX FREE 8CMX20M GREEN 1 EL IT NO NL PT DE DA 6/BOX	79993-01