

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:

Hypafix®

Basic UDI-DI:

40428094003292898

Intended purpose:

Hypafix® 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.

Date of Issue: 20.04.2023

Compiled and released:

Hamburg, 20.04.2023
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
71213-00000-06	LEUKOPLAST HYPAFIX 15CMX2M WHITE 1 IT PT ES	71213-00
71442-00000-06	HYPAFIX STICKER TIPS 2.5CMX5M WHITE 1 IT PL EN DE FR	71442-00
71442-00001-06	HYPAFIX STICKER TIPS 5CMX5M WHITE 1 DE EN PL IT FR	71442-01
71442-00002-06	HYPAFIX STICKER TIPS 10CMX5M WHITE 1 PL IT FR EN DE	71442-02
71442-00003-06	HYPAFIX 5CMX5M WHITE 1 EN IT ES	71442-03
71442-00004-06	HYPAFIX 10CMX5M WHITE 1 EN IT ES	71442-04
71442-00005-06	HYPAFIX 15CMX5M WHITE 1 EN IT ES	71442-05
71442-00006-06	HYPAFIX 20CMX5M WHITE 1 EN IT ES	71442-06
71443-00000-06	HYPAFIX 2.5CMX10M WHITE 1 IT PL FR EN DE	71443-00
71443-00001-06	HYPAFIX 5CMX10M WHITE 1 EN FR DE IT PT	71443-01
71443-00002-06	HYPAFIX 10CMX10M WHITE 1 EN FR DE IT PT	71443-02
71443-00003-06	HYPAFIX 15CMX10M WHITE 1 EN FR DE IT PT	71443-03
71443-00004-06	HYPAFIX 20CMX10M WHITE 1 EN FR IT PL DE	71443-04
71443-00005-06	HYPAFIX 30CMX10M WHITE 1 DE EN FR PL IT	71443-05
71444-00000-06	HYPAFIX STICKER TIPS 2.5CMX10M WHITE 1 PL IT FR EN DE	71444-00
71444-00001-06	HYPAFIX STICKER TIPS 5CMX10M WHITE 1 PL IT FR EN DE	71444-01
71444-00002-06	HYPAFIX STICKER TIPS 10CMX10M WHITE 1 PL IT FR EN DE	71444-02
71444-00003-06	HYPAFIX STICKER TIPS 15CMX10M WHITE 1 PL DE EN FR IT	71444-03
71444-00004-06	HYPAFIX STICKER TIPS 20CMX10M WHITE 1 IT DE PL FR EN	71444-04
71445-00026-06	HYPAFIX 5CMX1M WHITE 1 EN IT ES	71445-26
71449-00002-00	HYPAFIX 5CMX20M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	71449-02
71449-00003-00	HYPAFIX 10CMX20M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	71449-03
71449-00004-00	HYPAFIX 15CMX20M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	71449-04

Article	Description	REF
71449-00005-00	HYPAFIX 20CMX20M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	71449-05
71449-00006-00	HYPAFIX 30CMX20M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	71449-06
71449-00007-00	HYPAFIX 10CMX20M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV W.O. SPLIT	71449-07
71449-00008-00	HYPAFIX 15CMX20M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV W.O. SPLIT	71449-08
71449-00009-00	HYPAFIX 20CMX20M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV W.O. SPLIT	71449-09
71939-00000-06	HYPAFIX 10CMX2M WHITE 1 DE EN FR IT PL	71939-00
71939-00019-06	HYPAFIX 10CMX2M WHITE 1 EN IT PT ES PHARM	71939-19
71939-00020-06	HYPAFIX 15CMX2M WHITE 1 EN IT PT ES PHARM	71939-20
71939-00021-06	HYPAFIX 5CMX2M WHITE 1 EN IT PL FR DE	71939-21
71940-00000-06	HYPAFIX STICKER TIPS 10CMX2M WHITE 1 IT PL FR EN DE	71940-00
79949-00001-06	LEUKOPLAST HYPAFIX 5CMX10M WHITE 1 NL FR DE IT AT CH FR NL	79949-01
79949-00002-06	LEUKOPLAST HYPAFIX 5CMX10M WHITE 1 IT PT ES	79949-02
79949-00003-06	LEUKOPLAST HYPAFIX 5CMX10M WHITE 1 DA EN FI NO SV NORDIC	79949-03
79949-00004-06	LEUKOPLAST HYPAFIX 10CMX10M WHITE 1 NL FR DE IT AT CH FR NL	79949-04
79949-00005-06	LEUKOPLAST HYPAFIX 10CMX10M WHITE 1 IT PT ES	79949-05
79949-00007-06	LEUKOPLAST HYPAFIX 10CMX2M WHITE 1 NL FR DE IT AT CH FR NL	79949-07
79949-00008-06	LEUKOPLAST HYPAFIX 10CMX2M WHITE 1 IT PT ES	79949-08