

**Konformitätserklärung
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201**erklären in eigener Verantwortung,
dass das/die Produkt/e**Sangofix®
Sangofix® Air**

Transfusionsbestecke mit und ohne Entlüftung.

(Artikelnummern und Basic UDI-DI siehe Anlage I)

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745
übereinstimmt/übereinstimmen**Konformitätsbewertungsverfahren**
nach Anhang IX
der oben genannten Verordnung**Klassifizierung**
gemäß Anhang VIII der oben genannten
Verordnung
Klasse IIa**Benannte Stelle**
TÜV SÜD Product Service GmbH
Kennnummer 0123**Gültig bis**
gemäß gültigem EU Zertifikat
(Nr. G10 012974 0611)hereby declare in our own responsibility
that the product/s**Sangofix®
Sangofix® Air**Blood administration sets vented and non-
vented

(article numbers and Basic UDI-DI see attachment I)

is/are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745**Conformity Assessment Procedure**
according to annex IX
of the Regulation named above**Classification**
according to annex VIII of the Regulation named
above
Class IIa**Notified Body**
TÜV SÜD Product Service GmbH
Identification number 0123**Valid until**
according to our valid EU Certificate
(No. G10 012974 0611)

Anlage I / Attachment I**Basic UDI-DI 40392390000027342Z**

| Art.-Nr. / Art. No. | Produktname / Product name | Klasse / Class |
|----------------------------|-----------------------------------|-----------------------|
| 4052013 | Sangofix® | Ila |
| 4052013H | Sangofix® | Ila |
| 4053710 | Sangofix® | Ila |
| 4053710H | Sangofix® | Ila |
| 4146492 | Sangofix® | Ila |

Basic UDI-DI 403923900000039ZP

| Art.-Nr. / Art. No. | Produktname / Product name | Klasse / Class |
|----------------------------|-----------------------------------|-----------------------|
| 4034228 | Sangofix® | Ila |
| 4050151 | Sangofix® Air | Ila |
| 4051998 | Sangofix® | Ila |
| 4051998H | Sangofix® | Ila |
| 4052005 | Sangofix® | Ila |
| 4052005H | Sangofix® | Ila |
| 4052218H | Sangofix® | Ila |
| 4080187 | Sangofix® Air | Ila |
| 4100514 | Sangofix® | Ila |
| 4116011F | Sangofix® Air | Ila |
| 4117301 | Sangofix® | Ila |
| 4117549 | Sangofix® | Ila |

Document amendment information

| Version | Description of the changes |
|---------|---|
| 1.0 | First issue under Medical Device Regulation (MDR) |

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This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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