

**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 die Produkte**Intrapur®
Intrapur® Neonat
Intrapur® Lipid
Intrapur® Neonat Lipid
Sterifix®
Sterifix® Neonat
Infusionsfilter**Basis UDI-DI: 40392390000008082P
(Artikelnummern siehe Anlage I)mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745 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 products**Intrapur®
Intrapur® Neonat
Intrapur® Lipid
Intrapur® Neonat Lipid
Sterifix®
Sterifix® Neonat
Infusion filter**Basic UDI-DI: 40392390000008082P
(article numbers see attachment I)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: 4039239000008082P**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4099451	Intrapur [®] Neonat	Ila
4093216	Intrapur [®]	Ila
4184637	Sterifix [®]	Ila
4099354	Sterifix [®]	Ila
4099303	Sterifix [®]	Ila
4099257	Sterifix [®] Neonat	Ila
4099713	Intrapur [®]	Ila
4099703	Intrapur [®] Lipid	Ila
4183916	Intrapur [®]	Ila
4099800	Intrapur [®]	Ila
4099702	Intrapur [®]	Ila
4099460	Intrapur [®] Neonat Lipid	Ila

Document amendment information

Version	Description of the changes
1.0	Initial version under 2017/745 MDR

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