

**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**Pleurofix® No. 1, Pleurofix® No. 2**
Besteck zur Pleurapunktion
Basis UDI-DI: 4039239000007902V
(Artikelnummern siehe Anlage I)**Secretion bag**2-Liter-Sekretbeutel mit Luer-Lock-Konnektor für
Pleurofix® Nr. 1
Basis UDI-DI: 403923900000280ZW
(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
Klasse I steril**Benannte Stelle**
TÜV SÜD Product Service GmbH
Kennnummer 0123**Gültig bis**
gemäß gültigem EU Zertifikat
(G10 012974 0611, G11 012974 0626)hereby declare in our sole responsibility
that the products**Pleurofix® No. 1, Pleurofix® No. 2,**
Set for pleural puncture
Basis UDI-DI: 4039239000007902V
(article numbers see attachment I)**Secretion bag**Secretion bag 2 liters with luer-lock connector
for Pleurofix® No. 1
Basis UDI-DI: 403923900000280ZW
(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
Klasse IIa
Class I sterile**Notified Body**
TÜV SÜD Product Service GmbH
Identification number 0123**Valid until**
according to our valid EU Certificate
(G10 012974 0611, G11 012974 0626)

Anlage I / Attachment I**Basic UDI-DI 4039239000007902V****Art.-Nr. / Art. No. Produktname / Product name**

4461002 Pleurofix® No. 1

4461037 Pleurofix® No. 2

Klasse / Class

IIa / IIa

IIa / IIa

Basic UDI-DI 403923900000280ZW**Art.-Nr. / Art. No. Produktname / Product name**

4462009 Secretion bag

Klasse / Class

I steril / I sterile

Document amendment information

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

Title: Declaration of Conformity - 004-001-MDR - Pleurofix Initiator: Susanne ? Olbricht

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