

**Konformitätserklärung
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-00000201**erklären in eigener Verantwortung,
dass die Produkte**Aspiration Needle**Aspiration needle with filter for liquid drug
admixture Type Luer Lock
Basis UDI-DI: 40392390000023822Q
(Artikelnummern siehe Anlage I)**Aspiration Needle**Aspiration needle without filter for liquid drug
admixture Type Luer Lock
40392390000023812N
(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 I steril**Benannte Stelle**TÜV SÜD Product Service GmbH
Kennnummer 0123**Gültig bis**gemäß gültigem EU Zertifikat
(No. G11 012974 0626)hereby declare in our own responsibility
that the products**Aspiration Needle**Aspiration needle with filter for liquid drug
admixture Type Luer Lock
Basic UDI-DI: 40392390000023822Q
(article numbers see attachment I)**Aspiration Needle**Aspiration needle without filter for liquid drug
admixture Type Luer Lock
40392390000023812N
(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 I sterile**Notified Body**TÜV SÜD Product Service GmbH
Identification number 0123**Valid until**according to our valid EU Certificate
(No. G11 012974 0626)

Anlage I / Attachment I**Basic UDI-DI: 4039239000023822Q****Art.-Nr. / Art. No. Produktname / Product name**
8258821 Aspiration Needle**Klasse / Class**
I steril / I sterile**Basic UDI-DI: 4039239000023812N****Art.-Nr. / Art. No. Produktname / Product name**
8258813 Aspiration Needle**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 - 160-002-MDR - Aspiration Needle Initiator: Julia2 ? Mueller

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

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