

**Konformitätserklärung
Declaration of Conformity**

Wir

We

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

Verschlusskonus universal

IN-StopperVerschlussstopfen mit Zuspritzmöglichkeit
(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**

Klasse IIa

Benannte StelleTÜV 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**Combi-Stopper**

Universal Closing Stopper

IN-StopperClosure stopper with injection port
(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**

Class IIa

Notified BodyTÜV 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: 4039239000008112C**

| Art.-Nr. / Art. No. | Produktname / Product name | Klasse / Class |
|----------------------------|-----------------------------------|-----------------------|
| 4495101 | Combi-Stopper | Ila |
| 4495152 | Combi-Stopper | Ila |
| 4495209 | Combi-Stopper | Ila |
| 4495101R | Combi-Stopper | Ila |

Basic UDI-DI: 40392390000028583L

| Art.-Nr. / Art. No. | Produktname / Product name | Klasse / Class |
|----------------------------|-----------------------------------|-----------------------|
| 4238010 | IN-Stopper | Ila |
| 4238011 | IN-Stopper | Ila |

Document amendment information

| Version | Description of the changes |
|----------------|--|
| 1.0 | Initial version. |
| 2.0 | Addition of item numbers 4495209 and 4495101R. |

Title: Declaration of Conformity - 118-003 - MDR - Stopper Initiator: Daniela ? Schul

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

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