

**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-Stopper**
Verschlussstopfen 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 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**Combi-Stopper**
Universal Closing Stopper**IN-Stopper**
Closure 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 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: 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:

UserName: Schul, Daniela (schudnde)
Title: Senior Manager Regulatory Affairs CoE Infusion & Pain Therapy
Date: Monday, 29 April 2024, 15:48 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Monday, 29 April 2024, 18:04 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Tuesday, 30 April 2024, 08:25 W. Europe Daylight Time
Meaning: Approve Document
=====