

**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 das/die Produkt/e**Exadrop®**Präzisions-Tropfenregler mit Infusionsgerät.
Nur für Schwerkraftinfusionen.
Basis UDI-DI: 40392390000026627**Exadrop®**Präzisions-Tropfenregler für Infusionsgerät.
Nur für Schwerkraftinfusionen.
Basis UDI-DI: 40392390000025902Z

(Artikelnummern siehe Anlage I)

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745
übereinstimmt/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
(Nr. G11 012974 0626)hereby declare in our own responsibility
that the product/s**Exadrop®**Precision flow control device with I.V.
administration set. Only for gravity infusion.
Basic UDI-DI: 40392390000026627**Exadrop®**Precision flow control device. Only for gravity
infusion.
Basic UDI-DI: 40392390000025902Z

(article numbers 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**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 40392390000026627**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4061209	Exadrop®	I steril / I sterile
4061225	Exadrop®	I steril / I sterile
4061276	Exadrop®	I steril / I sterile
4061284	Exadrop®	I steril / I sterile
4062264	Exadrop®	I steril / I sterile
4180330	Exadrop®	I steril / I sterile
4188144	Exadrop®	I steril / I sterile

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Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4061306	Exadrop®	I steril / I sterile

Document amendment information

Version	Description of the changes
1.0	First issue under Medical Device Regulation (MDR)

Title: Declaration of Conformity - 106-003 - MDR - Exadrop Initiator: Meike ? Junius

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

UserName: Junius, Meike (junimede)
Title: Manager Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 15 May 2024, 11:40 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 15 May 2024, 12:00 W. Europe Daylight Time
Meaning: Approve Document

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Wednesday, 15 May 2024, 17:40 W. Europe Daylight Time
Meaning: Approve Document
