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: 403923900000026627

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: 403923900000026627

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)

Effective

Anlage I / Attachment I

Basic UDI-DI 403923900000026627

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

Basic UDI-DI 40392390000025902Z

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
==========

Effective