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®
Exadrop® SafeSet
Präzisions-Tropfenregler mit Infusionsgerät.
Nur für Schwerkraftinfusionen.
Basis UDI-DI: 40392390000002692D

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®
Exadrop® SafeSet
Precision flow control device with I.V. administration set. Only for gravity infusion.
Basic UDI-DI: 40392390000002692D

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 40392390000002692D

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
4186719	Exadrop® SafeSet	I steril / I sterile
4186720	Exadrop® SafeSet	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)
2.0	Correction of Basic UDI-DI: 403923900000026627 to Basic UDI-DI: 40392390000002692D
3.0	Addition of product name “Exadrop® SafeSet” and Art. No. 4186719 and 4186720 to Basic UDI-DI 40392390000002692D

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:

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