

**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: 40392390000002692D**Exadrop®**Präzisions-Tropfenregler für Infusionsgerät.  
Nur für Schwerkraftinfusionen.  
Basis UDI-DI: 403923900000025902Z

(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: 40392390000002692D**Exadrop®**Precision flow control device. Only for gravity  
infusion.  
Basic UDI-DI: 403923900000025902Z

(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 4039239000002692D**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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

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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