

## 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 die Produkte

**Infuvalve®**  
**Infuvalve® C**

Rückschlagventil. Zur Rückflussverhinderung in  
Infusionsleitungen bei Parallelinfusion.

Basis UDI-DI: 40392390000008102A  
(Artikelnummern siehe Anlage I)

mit den Anforderungen der Medizinprodukte  
Verordnung (EU) 2017/745 übereinstimmen

**Konformitätsbewertungsverfahren**  
nach Anhang IX  
der oben genannten Verordnung

**Klassifizierung**  
gemäß Anhang VIII der oben genannten  
Verordnung  
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 products

**Infuvalve®**  
**Infuvalve® C**

Back-check valve. To prevent back flow into  
infusion lines.

Basic UDI-DI: 40392390000008102A  
(article numbers see attachment I)

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 IIa

**Notified Body**  
TÜV SÜD Product Service GmbH  
Identification number 0123

**Valid until**  
according to our valid EU Certificate  
(Nr. G10 012974 0611)

### Anlage I / Attachment I

**Basic UDI-DI: 4039239000008102A**

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

4094000N	Infuvalve®	IIa
4094000C	Infuvalve® C	IIa

### Document amendment information

Version	Description of the changes
1.0	Initial version under MDR

Title: Declaration of Conformity - 118-002 - MDR - Infuvalve.doc Initiator: Sandra ? Staufenberg

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

UserName: Staufenberg, Sandra (stausade)  
Title: Administrator Regulatory Affairs CoE Infusion & Pain Therapy  
Date: Monday, 25 March 2024, 08:56 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, 25 March 2024, 14:34 W. Europe Daylight Time  
Meaning: Approve Document

---

UserName: Seidel, Stefan (seidstde)  
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy  
Date: Monday, 25 March 2024, 15:22 W. Europe Daylight Time  
Meaning: Approve Document

---