

**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 die Produkte

Discofix® C

Mehrwegehähne und Hahnbanke für
Infusionstherapie

Basis UDI-DI: 403923900000075933
(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

Discofix® C

Stopcocks and manifolds for infusion therapy

Basic UDI-DI: 403923900000075933
(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
(No. G10 012974 0611)

Effective

Anlage I / Attachment I**Basic UDI-DI: 403923900000075933**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
16494C	Discofix® C	Ila
RU16494C	Discofix® C	Ila
CN16494C	Discofix® C	Ila
EC16494C	Discofix® C	Ila
16494CSF	Discofix® C	Ila
16494C-01	Discofix® C	Ila
16495C	Discofix® C	Ila
RU16495C	Discofix® C	Ila
16495CSF	Discofix® C	Ila
16496C	Discofix® C	Ila
RU16496C	Discofix® C	Ila
CN16496C	Discofix® C	Ila
BR16496C	Discofix® C	Ila
16497C	Discofix® C	Ila
16500C	Discofix® C	Ila
16500CSF	Discofix® C	Ila
16500CSF-1	Discofix® C	Ila
16501C	Discofix® C	Ila
16501CSF	Discofix® C	Ila
16501CSF-1	Discofix® C	Ila
16502C	Discofix® C	Ila
16503C	Discofix® C	Ila
16504C	Discofix® C	Ila
16520C	Discofix® C	Ila
16520CSF	Discofix® C	Ila
16540C	Discofix® C	Ila
16540CSF	Discofix® C	Ila
16551C	Discofix® C	Ila
16551CSF	Discofix® C	Ila
16560C	Discofix® C	Ila
16560CSF	Discofix® C	Ila
16600C	Discofix® C	Ila
16605C	Discofix® C	Ila
16608C	Discofix® C	Ila
16609C	Discofix® C	Ila
16610C	Discofix® C	Ila
16611C	Discofix® C	Ila
16612C	Discofix® C	Ila
16613C	Discofix® C	Ila

16614C	Discofix® C	Ila
16615C	Discofix® C	Ila
16700C	Discofix® C	Ila
16701C	Discofix® C	Ila
16720C	Discofix® C	Ila
16740C	Discofix® C	Ila
16751C	Discofix® C	Ila
16760C	Discofix® C	Ila
16800C	Discofix® C	Ila
16801C	Discofix® C	Ila
16900C	Discofix® C	Ila
16901C	Discofix® C	Ila

Document amendment information

Version	Description of the changes
1.0	Initial version under 2017/745 MDR

Title: Declaration of Conformity - 111-002-MDR - Discofix C Initiator: Julia2 ? Mueller

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

UserName: Mueller, Julia2 (hampjude)

Title: Senior Manager Regulatory Affairs CoE Infusion & Pain Therapy

Date: Tuesday, 21 May 2024, 11:22 W. Europe Daylight Time

Meaning: Document signed as Author

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UserName: Seidel, Stefan (seidstde)

Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy

Date: Tuesday, 21 May 2024, 11:58 W. Europe Daylight Time

Meaning: Approve Document

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UserName: Brand, Thomas (brantode)

Title: HC-QM-DE08 Vice President QM for non-active Medical Devices

Date: Tuesday, 21 May 2024, 17:55 W. Europe Daylight Time

Meaning: Approve Document

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