

Konformitätserklärung Declaration of Conformity

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany**

erklären in eigener Verantwortung,
dass das/die Produkt/e

**Discofix®,
Discofix® C**

Hahnbanksysteme für Infusionstherapie und
Monitoring

Mehrwegehähne für Infusionstherapie
und Monitoring

Mehrwegehähne mit Leitung für
Infusionstherapie

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

Richtlinie 93/42/EWG des Rates vom 14. Juni
1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG

Konformitätsbewertungsverfahren
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123

hereby declare in our own responsibility
that the product/s

**Discofix®,
Discofix® C**

Stopcock manifolds for infusion therapy and
monitoring

Multidirectional stopcocks for infusion therapy
and monitoring

Multidirectional stopcocks with tubing for
infusion therapy

(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June
1993
concerning Medical Devices
amended by Directive 2007/47/EC

Conformity Assessment Procedure
according to annex II (excluding section 4)
of the Council Directive named above

Classification
according to annex IX of the
Council Directive named above
Class IIa

Notified Body
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123

Datum der ersten CE-Kennzeichnung

1994-12

Gültig bis

2024-05-26

Date of first CE-marking

1994-12

Valid until

2024-05-26

Effective

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
BR16496C	Discofix® C	Ila
CN16494C	Discofix® C	Ila
CN16496C	Discofix® C	Ila
EC16494C	Discofix® C	Ila
RU16494C	Discofix® C	Ila
V540K69B	Discofix®	Ila
V540K75B	Discofix®	Ila
15809	Discofix®	Ila
15895	Discofix®	Ila
15896	Discofix®	Ila
15897	Discofix®	Ila
15898	Discofix®	Ila
15899	Discofix®	Ila
16466	Discofix®	Ila
16494C-01	Discofix® C	Ila
16494C	Discofix® C	Ila
16494CSF	Discofix® C	Ila
16495C	Discofix® C	Ila
16495CSF	Discofix® C	Ila
16496C	Discofix® C	Ila
16497C	Discofix® C	Ila
16500C	Discofix® C	Ila
16500CSF	Discofix® C	Ila
16501C	Discofix® C	Ila
16501CSF	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

Effective

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
16600CSF	Discofix® C	Ila
16605C	Discofix® C	Ila
16608C	Discofix® C	Ila
16608CSF	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
409511CN	Discofix®	Ila
409512CN	Discofix®	Ila
409810CN	Discofix®	Ila
409821CN	Discofix®	Ila
4082060	Discofix®	Ila
4095111	Discofix®	Ila
4095111IN	Discofix®	Ila
4095120	Discofix®	Ila
4095138	Discofix®	Ila
4095146	Discofix®	Ila
4095146IN	Discofix®	Ila
4098080	Discofix®	Ila
4098102	Discofix®	Ila
4098103	Discofix®	Ila
4098218	Discofix®	Ila
4098234	Discofix®	Ila
4098250	Discofix®	Ila
4098501	Discofix®	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4099010	Discofix®	Ila
4099117	Discofix®	Ila
4591496	Discofix®	Ila
4597532	Discofix®	Ila

Amendment Information

Version	Description of the changes
28	Add Art. no. 16700C, 16701C, 16720C, 16740C, 16751C, 16760C
29	Add Art. no. 4098103
30	Add Art. no. CN16494C, CN16496C, RU16494C
31	End of Life DIV 540 Delete Art. no. 16454, 4083032, 4083059, 4083261, 4083377, 4083407, 4083415, 4083660, 4084551, 4085434, 4085450, 4086694, 4087518, 4087844, 4088557, 4288300, 4288459
32	Add Art. no. 16502C, 16503C, 16504C

Title: Declaration of Conformity - 39.05.050 - Discofix Initiator: Caroline ? Herbst

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

UserName: Herbst, Caroline (fuehcade)
Title: Administrator Regulatory Affairs
Date: Friday, 27 March 2020, 12:11 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: Friday, 27 March 2020, 13:09 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Seidel, Stefan (seidstde)
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems
Date: Friday, 27 March 2020, 16:22 W. Europe Daylight Time
Meaning: Approve Document
=====