

**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**Discifix®,
Discifix® C**Hahnbanksysteme für Infusionstherapie und
MonitoringMehrwegehähne für Infusionstherapie
und MonitoringMehrwegehähne mit Leitung für
Infusionstherapie

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 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 0123hereby declare in our own responsibility
that the product/s**Discifix®,
Discifix® C**Stopcock manifolds for infusion therapy and
monitoringMultidirectional stopcocks for infusion therapy
and monitoringMultidirectional 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

Date of first CE-marking

1994-12

Gültig bis
2024-05-26

Valid until
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
15809	Discifix®	Ila
15895	Discifix®	Ila
15896	Discifix®	Ila
15897	Discifix®	Ila
15898	Discifix®	Ila
15899	Discifix®	Ila
16466	Discifix®	Ila
16494C	Discifix® C	Ila
16494C-01	Discifix® C	Ila
16494CCS	Discifix® C	Ila
16494CSF	Discifix® C	Ila
16495C	Discifix® C	Ila
16495CSF	Discifix® C	Ila
16496C	Discifix® C	Ila
16497C	Discifix® C	Ila
16500C	Discifix® C	Ila
16500CCS	Discifix® C	Ila
16500CSF	Discifix® C	Ila
16500CSF-1	Discifix® C	Ila
16501C	Discifix® C	Ila
16501CSF	Discifix® C	Ila
16501CSF-1	Discifix® C	Ila
16502C	Discifix® C	Ila
16503C	Discifix® C	Ila
16504C	Discifix® C	Ila
16520C	Discifix® C	Ila
16520CSF	Discifix® C	Ila
16540C	Discifix® C	Ila
16540CSF	Discifix® C	Ila
16551C	Discifix® C	Ila
16551CSF	Discifix® C	Ila
16560C	Discifix® C	Ila
16560CSF	Discifix® C	Ila
16600C	Discifix® C	Ila
16600CSF	Discifix® C	Ila
16605C	Discifix® C	Ila
16608C	Discifix® C	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
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
4082060	Discofix®	Ila
4095111	Discofix®	Ila
4095111IN	Discofix®	Ila
409511CN	Discofix®	Ila
4095120	Discofix®	Ila
409512CN	Discofix®	Ila
4095138	Discofix®	Ila
4095146	Discofix®	Ila
4095146IN	Discofix®	Ila
4098080	Discofix®	Ila
4098102	Discofix®	Ila
4098103	Discofix®	Ila
409810CN	Discofix®	Ila
4098218	Discofix®	Ila
409821CN	Discofix®	Ila
4098234	Discofix®	Ila
4098250	Discofix®	Ila
4098501	Discofix®	Ila
4099010	Discofix®	Ila
4099117	Discofix®	Ila
4591496	Discofix®	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4597532	Discofix®	Ila
BR16496C	Discofix® C	Ila
CN16494C	Discofix® C	Ila
CN16496C	Discofix® C	Ila
EC16494C	Discofix® C	Ila
RU16494C	Discofix® C	Ila
RU16495C	Discofix® C	Ila
RU16496C	Discofix® C	Ila

Amendment Information

Version	Description of changes
32.0	Add Art. no. 16502C, 16503C, 16504C
33.0	Add Art. no. 16494CCS, 16500CCS
34.0	Delete out of market art. no. V540K75B, V540K69B
35.0	Add Art. no. RU16495C, RU16496C
36.0	Add Art. no. 16500CSF-1, 16501CSF-1

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
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Meaning: Document signed as Author
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UserName: Brand, Thomas (brantode)
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Date: Monday, 10 May 2021, 09:12 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Seidel, Stefan (seidstde)
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Date: Wednesday, 12 May 2021, 14:30 W. Europe Daylight Time
Meaning: Approve Document
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