

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

Kundenspezifische Sets

(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

Datum der ersten CE-Kennzeichnung

1994-12

Gültig bis

2024-05-26

hereby declare in our own responsibility
that the product/s

Customized Kits

(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

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
4083254	ProSet Discofix® C Hahnbank-Set 5-fach bunt	Ila
4083255	ProSet Discofix®C Hahnbank-Set 5-fach bunt	Ila
4083777	ProSet Discofix® C Hahnbank-Set 5-fach bunt	Ila
4084128	ProSet Discofix®-Hahnbank-Set 3-fach	Ila
4084136	ProSet Infusions-Set	Ila
4084497	ProSet Discofix®C Hahnbank-Set 5-fach	Ila
4084510	ProSet Discofix® C Hahnbank-Set 5-fach	Ila
4084792	ProSet Discofix® C Hahnbank Set 5-fach	Ila
4085060	ProSet Discofix® Hahnbank-Set 3-fach	Ila
4085086	ProSet Discofix®C Hahnbank-Set 3-fach	Ila
4085129	ProSet Verbindungsleitung	Ila
4085168	ProSet Discofix® C Hahnbank-Set 3-fach bunt	Ila
4085213	ProSet Discofix®-Hahnbank-Set 3-fach	Ila
4085230	ProSet Discofix®-Hahnbank-Set 5-fach	Ila
4085300SF	ProSet Discofix®C Hahnbank 3-fach	Ila
4085434SF	ProSet Discofix®C Hahnbank 3-fach Set bunt	Ila
4085450SF	ProSet Discofix®C -Hahnbank 5-fach Set bunt	Ila
4085500SF	ProSet Discofix®C Hahnbank 5-fach	Ila
4085698	ProSet Discofix®-Dreiwegehahn	Ila
4085739	ProSet Discofix® C-3 blau 100lg	Ila
4086074	ProSet Discofix®C Hahnbank-Set 5-fach	Ila
4086481	ProSet Discofix®-Hahnbank- Set 3-fach	Ila
4086482	ProSet Discofix® C Hahnbank-Set 3-fach bunt	Ila
4086879	ProSet Discofix®C Hahnbank Set 3-fach	Ila
4086945	ProSet Discofix® C Hahnbank-Set 5-fach	Ila
4087135	ProSet Infusions-Set	Ila
4087780	ProSet Infusions-Set	Ila
4087917	ProSet Discofix® C Hahnbank-Set 5-fach	Ila
4087930	ProSet Discofix® C-Hahnbank-Set 3-fach	Ila
4088190	ProSet Discofix®-Hahnbank-Set 5-fach	Ila
4088520	ProSet Discofix® C-Hahnbank-Set 5-fach	Ila
4088549	ProSet Discofix®C Hahnbank Set 3-fach	Ila
4088560	ProSet Discofix® C Hahnbank-Set 5-fach	Ila
4088590	ProSet Infusions-Set	Ila
4088696	ProSet Discofix® C Hahnbank-Set 3-fach	Ila
4088698	ProSet Discofix® C Hahnbank-Set 5-fach bunt	Ila
4088699	ProSet Discofix® C-Hahnbank-Set 5-fach bunt	Ila
4089464	ProSet Discofix® C Hahnbank-Set 3-fach	Ila
4089529	ProSet Infusions-Set	Ila
4089871	ProSet Discofix® C Hahnbank-Set 5-fach bunt	Ila
4092189	ProSet Discofix® C	Ila
4092190	ProSet Discofix® C	Ila
4092996	ProSet Discofix®-Dreiwegehahn	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4095103	ProSet Discofix®-Dreiwegehahn	Ila
4097159	ProSet WCS Infusions Set	Ila
4097688	ProSet Discofix®-Dreiwegehahn	Ila
4098005	ProSet Discofix®-Dreiwegehahn weiss	Ila
4180019SP	ProSet Discofix® C Hahnbank Set 3-fach	Ila
4180020SP	ProSet Discofix® C Hahnbank Set 5-fach	Ila
4180127	ProSet Discofix® C Hahnbank-Set 5-fach	Ila
4180300	ProSet Discofix®C Hahnbank-Set 5-fach	Ila
4180306	ProSet Discofix® C Hahnbank-Set 5-fach bunt	Ila
4180437	ProSet Discofix® C-Dreiwegehahn rot	Ila
4180438	ProSet Discofix® C Dreiwegehahn blau	Ila
4180445	ProSet Discofix® C Hahnbank-Set 3-fach bunt	Ila
4180488	ProSet Infusions-Set	Ila
4180631SP	ProSet Discofix® C Hahnbank-Set 5-fach	Ila
4180677	ProSet Discofix®C Hahnbank-Set 11-fach	Ila
4180678	ProSet Discofix® C Hahnbank-Set 8-fach	Ila
4180679	ProSet Discofix® C Hahnbank-Set 3-fach	Ila
4180965	ProSet Discofix®-Hahnbank-Set 5-fach	Ila
4181027	ProSet Discofix® C Hahnbank-Set 3-fach bunt	Ila
4181081	ProSet Discofix®C Dreiwegehahn Set	Ila
4181140	ProSet Discofix®-Hahnbank-Set 3-fach	Ila
4181232	ProSet Discofix®C Hahnbank-Set 3-fach	Ila
4181360	ProSet Infusions-Wechselset	Ila
4181778	ProSet Discofix® C-Hahnbank-Set 5-fach	Ila
4181905	ProSet Discofix® C Hahnbank-Set 3-fach bunt	Ila
4182040	ProSet Discofix®-Hahnbank-Set 5-fach	Ila
4182181	ProSet Intrafix® SafeSet	Ila
4182182	ProSet Infusions-Set	Ila
4182190SP	ProSet Discofix®C-Hahnbank-Set 3-fach	Ila
4182308	ProSet Discofix®C Hahnbank-Set 5-fach	Ila
4182398	ProSet Discofix® C-Hahnbank Set 5-fach	Ila
4182399	ProSet Discofix® C Hahnbank-Set 3-fach	Ila
4182488	ProSet Discofix® C-Hahnbank Set 5-fach	Ila
4182502	ProSet High-Flow Dreiweg weiß	Ila
4182556	ProSet Infusions-Set	Ila
4182633	ProSet Discofix® C Hahnbank-Set 3-fach bunt	Ila
4182635	ProSet Discofix® C Hahnbank-Set 5-fach bunt	Ila
4182639	ProSet Discofix® C Hahnbank-Set 3-fach bunt	Ila
4182651	ProSet Discofix® C-Hahnbank-Set	Ila
4182652	ProSet Discofix® C Hahnbank-Set	Ila
4182719	ProSet Discofix® C Hahnbank-Set 3-fach blau	Ila
4182720	ProSet Discofix®C Hahnbank-Set 3-fach bunt	Ila
4182737	ProSet Discofix® C-Hahnbank-Set 5-fach	Ila
4182880	ProSet Discofix® Hahnbank Set 3-fach	Ila
4182944	ProSet Discofix® C Hahnbank-Set 5-fach bunt	Ila
4182952	ProSet Infusions-Set	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4183088	ProSet Discofix® C Hahnbank-Set 5-fach	Ila
4183312	ProSet Discofix®C Hahnbank Set 3-fach	Ila
4183371	ProSet Discofix®C Hahnbank-Set 5-fach	Ila
4183510	ProSet Discofix®C Hahnbank-Set 3-fach bunt	Ila
4183719	ProSet Infusions-Set	Ila
4183777	ProSet Discofix®C-Hahnbank-Set 3-fach	Ila
4183787	ProSet Discofix®C-Hahnbank-Set 5-fach	Ila
4183851	ProSet Discofix®C-Hahnbank-Set 3-fach	Ila
4183852	ProSet Discofix® C-Hahnbank-Set 3-fach	Ila
4183919	ProSet Infusions-Set	Ila
4183926	ProSet Infusions-Set	Ila
4183927	ProSet Infusions-Set	Ila
4183938	ProSet Infusions-Set	Ila
4183941	ProSet Infusions-Set	Ila
4183942	ProSet Infusions-Set	Ila
4183943	ProSet Infusions-Set	Ila
4183945	ProSet Infusions-Set	Ila
4184005	ProSet Infusions-Set	Ila
4184246	ProSet Discofix®-Hahnbank-Set 5-fach	Ila
4184327	ProSet Discofix® C Hahnbank-Set 5-fach bunt	Ila
4184360	ProSet Infusions-Set	Ila
4184424	ProSet Infusions-Set	Ila
4184440	ProSet Hahnbank-Set 3 B	Ila
4184459	Infusions-Set	Ila
4184483	ProSet Discofix® C Hahnbank-Set 5-fach	Ila
4184491	ProSet Discofix® C Hahnbank-Set 5-fach blau	Ila
4184521	ProSet Discofix®C Hahnbank-Set 3A	Ila
4184817	ProSet Discofix®C Hahnbank-Set 3-fach bunt	Ila
4184963	ProSet Discofix®-Hahnbank-Set 3-fach	Ila
4185021	ProSet Discofix®C Hahnbank Set 5-fach	Ila
4185048	ProSet Discofix®-Hahnbank-Set 5-fach	Ila
4185366	ProSet Discofix®C Hahnbank Set 3-fach	Ila
4185447	ProSet Discofix®C Hahnbank-Set 3-fach bunt	Ila
4185449	ProSet Discofix®C Hahnbank-Set 3-fach	Ila
4185501	ProSet Discofix®-Hahnbank-Set 3-fach	Ila
4185510	ProSet Discofix®-Hahnbank-Set 3-fach	Ila
4185579	ProSet Infusions-Set	Ila
4185687	ProSet Infusions-Set	Ila
4185821N	ProSet Discofix®C Hahnbank 5-fach Set	Ila
4185875	ProSet Infusions-Set	Ila
4185927	ProSet Discofix® C-Hahnbank Set 5-fach	Ila
4185928	ProSet Discofix® C Hahnbank-Set 3-fach blau	Ila
4185972	ProSet Discofix®C Hahnbank Set 5-fach	Ila
4185985	ProSet Discofix®C Hahnbank-Set 3-fach bunt	Ila
4186097	ProSet Intrafix® SafeSet	Ila
4186110	ProSet Intrafix® SafeSet	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4186206	ProSet Discifix® C Hahnbank Set 3-fach	Ila
4186505	ProSet Discifix® C Hahnbank 3-fach Set	Ila
4186567	ProSet Discifix®-Hahnbankt 5-fach	Ila
4186579	ProSet Discifix® C Hahnbank Set 3/5 fach	Ila
4186580	ProSet Discifix®C Hahnbank-Set	Ila
4186711	ProSet Infusions-Set	Ila
4186925	ProSet Discifix®C Dreiwegehahn Set gelb	Ila
4186950	ProSet Infusions-Set	Ila
4186950	ProSet Infusions-Set	Ila
4186980	ProSet Intrafix® SafeSet	Ila
4186980	ProSet Intrafix® SafeSet	Ila
4186981	ProSet Intrafix® SafeSet	Ila
4187008	ProSet TIVA-Set	Ila
4187010	ProSet TIVA-Set	Ila
4187011	ProSet Intrafix® SafeSet	Ila
4187032	ProSet Infusions-Set	Ila
4187033	ProSet Infusions-Set	Ila
4187070	ProSet Discifix®C Dreiwegehahn Set gelb	Ila
4187199	ProSet Discifix®C Hahnbank-Set 3-fach gelb	Ila
4187202	ProSet Discifix®-Hahnbank-Set 3-fach	Ila
4187203	ProSet Discifix® C Hahnbank-Set 3-fach - weiß	Ila
4187204	ProSet Discifix®C Hahnbank-Set 3-fach bunt	Ila
4187290	ProSet Discifix® C Hahnbank 3x5-fach Set	Ila
4187291	ProSet Discifix®C Hahnbank 9-fach Set	Ila
4187391	ProSet Infusions-Set	Ila
4187468	ProSet Infusions-Set	Ila
4187469	ProSet Infusions-Set	Ila
4187504	ProSet Intrafix® SafeSet	Ila
4187527	ProSet Infusions-Set	Ila
4187750	ProSet Infusions-Set	Ila
4187823	ProSet Infusions-Set	Ila
4187826	ProSet Discifix®-Hahnbank-Set 5-fach	Ila
4187831	ProSet Discifix®C-Hahnbank-Set 5-fach	Ila
4187834	ProSet Discifix® C-Hahnbank-Set 3-fach	Ila
4187838	ProSet Discifix® C Hahnbank-Set 5-fach bunt	Ila
4187865	ProSet Infusions-Set	Ila
4187878	ProSet Discifix® C-Hahnbank-Set 5-fach	Ila
4187879	ProSet Discifix® C-Hahnbank-Set 3-fach	Ila
4187884	ProSet Discifix® C 3-fach (10 Stück)	Ila
4187898	ProSet Discifix®C Dreiwegehahn Set	Ila
4187911	ProSet Discifix® C-Dreiwegehahn Set	Ila
4187913	ProSet Discifix® C-Dreiwegehahn Set	Ila
4187954	ProSet Discifix®-Hahnbank-Set 5-fach	Ila
4188004	ProSet Discifix®C Hahnbank-Set 3-fach	Ila
4188047	ProSet Discifix®-Dreiwegehahn Set	Ila
4188071	ProSet Discifix®-Hahnbank Set 8-fach	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4188072	ProSet Discofix®C Hahnbank-Set 3/3-fach	Ila
4188080	ProSet Infusions-Set	Ila
4188105	ProSet Discofix® Hahnbank Set 5-fach	Ila
4188109	ProSet Intrafix® SafeSet	Ila
4188113	ProSet Intrafix® SafeSet	Ila
4188116	ProSet Intrafix® SafeSet	Ila
4188138	ProSet Intrafix® SafeSet	Ila
4188188	ProSet Discofix® C-Hahnbank-Set 5-fach	Ila
4188189	ProSet Discofix® C-Hahnbank-Set 5-fach	Ila
4188225	ProSet Discofix®C Hahnbank-Set	Ila
4188510	ProSet Discofix® C Hahnbank Set 3-fach	Ila
4188957	ProSet Discofix®-Hahnbank-Set 6-fach	Ila
4188958	ProSet Discofix®C Hahnbank-Set 8-fach	Ila
4188959	ProSet Discofix®-Hahnbank-Set 3-fach	Ila
4188960	ProSet Discofix®-Hahnbank- Set 3-fach	Ila
4189109	ProSet Intrafix® SafeSet	Ila
4189821	ProSet Discofix® C Hahnbank-Set 5-fach bunt	Ila
4189839	ProSet Discofix® C Hahnbank-Set 5-fach blau	Ila
4189847	ProSet Discofix® C Hahnbank-Set 5-fach blau	Ila
4890078	ProSet Pumpenfüll-Set	Ila

Amendment Information

Version	Description of the changes
40.0	Add art. no. 4183926 and 4182488 (former covered by DoC 39.05.008KIT) Change Product Name of art. no. 4085434SF, 4085450SF, 4087917
41.0	Add art. no. 4085500SF, 4085300SF, 4184518, 4182651, 4182652 Change Product Name of art. no. 4182720, 4187199
42.0	Delete art. no. 4184518 Change product name of art. no. 4186580 from "ProSet Discofix®C Hahnbank-Set 3/5-fach" to "ProSet Discofix®C Hahnbank-Set" Add art. no. 4187834 former covered by 39.05.009KIT Delete out of Market art. no. 4087100, 4185862, 4084791, 4185625, 4183401, 4085159, 4089227, 4187830, 4188012, 4182845, 4180380, 4181115, 4086850, 4180194, 4187490, 4087410, 4089782, 4181026, 4181751, 4182316, 4182754, 4184886, 4185262, 4185986, 4186578, 4188217, 4082893, 4083776, 4084179, 4084276, 4085183, 4085221, 4087631, 4182634, 4182764, 4183886, 4185528, 4185987, 4187261, 4083131, 4083903, 4089575, 4180747, 4187300, 4182397
43.0	Change product name of art. no. 4086879 from "ProSet Discofix®-Hahnbank Set 3-fach" to "ProSet Discofix®C Hahnbank Set 3-fach" Add art. no. 4183945, 4189109, 4187204, 4088699, 4187823, 4183942
44.0	Add art. no. 4097159, 4185449

Title: Declaration of Conformity - 39.05.050KIT - Discifix ProSet 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: Wednesday, 24 June 2020, 08:46 W. Europe Daylight Time
Meaning: Document signed as Author
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