

## 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 14<sup>th</sup> 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

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4083254	ProSet Discifix® C Hahnbank-Set 5-fach bunt	Ila
4083255	ProSet Discifix®C Hahnbank-Set 5-fach bunt	Ila
4083777	ProSet Discifix® C Hahnbank-Set 5-fach bunt	Ila
4084128	ProSet Discifix®-Hahnbank-Set 3-fach	Ila
4084497	ProSet Discifix®C Hahnbank-Set 5-fach	Ila
4084510	ProSet Discifix® C Hahnbank-Set 5-fach	Ila
4084792	ProSet Discifix® C Hahnbank Set 5-fach	Ila
4085086	ProSet Discifix®C Hahnbank-Set 3-fach	Ila
4085129	ProSet Verbindungsleitung	Ila
4085168	ProSet Discifix® C Hahnbank-Set 3-fach bunt	Ila
4085213	ProSet Discifix®-Hahnbank-Set 3-fach	Ila
4085230	ProSet Discifix®-Hahnbank-Set 5-fach	Ila
4085300SF	ProSet Discifix®C Hahnbank 3-fach	Ila
4085434SF	ProSet Discifix®C Hahnbank 3-fach Set bunt	Ila
4085450SF	ProSet Discifix®C -Hahnbank 5-fach Set bunt	Ila
4085500SF	ProSet Discifix®C Hahnbank 5-fach	Ila
4085600SF	ProSet Discifix® C	Ila
4085698	ProSet Discifix®-Dreiwegehahn	Ila
4085700SF	ProSet Discifix® C	Ila
4085739	ProSet Discifix® C-3 blau 100lg	Ila
4085800SF	ProSet Discifix® C	Ila
4085900SF	ProSet Discifix® C	Ila
4086074	ProSet Discifix®C Hahnbank-Set 5-fach	Ila
4086481	ProSet Discifix®-Hahnbank- Set 3-fach	Ila
4086482	ProSet Discifix® C Hahnbank-Set 3-fach bunt	Ila
4086879	ProSet Discifix®C Hahnbank Set 3-fach	Ila
4086945	ProSet Discifix® C Hahnbank-Set 5-fach	Ila
4087135	ProSet Infusions-Set	Ila
4087780	ProSet Infusions-Set	Ila
4087917	ProSet Discifix® C Hahnbank-Set 5-fach	Ila
4087930	ProSet Discifix® C-Hahnbank-Set 3-fach	Ila
4088190	ProSet Discifix®-Hahnbank-Set 5-fach	Ila
4088520	ProSet Discifix® C-Hahnbank-Set 5-fach	Ila
4088560	ProSet Discifix® C Hahnbank-Set 5-fach	Ila
4088590	ProSet Infusions-Set	Ila
4088696	ProSet Discifix® C Hahnbank-Set 3-fach	Ila
4088698	ProSet Discifix® C Hahnbank-Set 5-fach bunt	Ila
4088699	ProSet Discifix® C-Hahnbank-Set 5-fach bunt	Ila
4089464	ProSet Discifix® C Hahnbank-Set 3-fach	Ila
4089529	ProSet Infusions-Set	Ila
4095103	ProSet Discifix®-Dreiwegehahn	Ila
4097152	PROSET WCS Infusions-Set PVC	Ila
4097153	ProSet Discifix® C	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4097155	ProSet Discifix® C	Ila
4097156	ProSet Discifix® C	Ila
4097158	ProSet Discifix® C	Ila
4097159	PROSET WCS Infusions-Set PUR/PVC	Ila
4097160	ProSet Discifix® C	Ila
4097161	ProSet Discifix® C	Ila
4097162	PROSET WCS Infusions-Set PUR	Ila
4097163	ProSet Discifix® C	Ila
4097164	ProSet Discifix® C	Ila
4097688	ProSet Discifix®-Dreiwegehahn	Ila
4098005	ProSet Discifix®-Dreiwegehahn weiss	Ila
4180019SP	ProSet Discifix® C Hahnbank Set 3-fach	Ila
4180020SP	ProSet Discifix® C Hahnbank Set 5-fach	Ila
4180120	ProSet Discifix®C-Hahnbank-Set 3-fach	Ila
4180127	ProSet Discifix® C Hahnbank-Set 5-fach	Ila
4180300	ProSet Discifix®C Hahnbank-Set 5-fach	Ila
4180306	ProSet Discifix® C Hahnbank-Set 5-fach bunt	Ila
4180437	ProSet Discifix® C-Dreiwegehahn rot	Ila
4180438	ProSet Discifix® C Dreiwegehahn blau	Ila
4180445	ProSet Discifix® C Hahnbank-Set 3-fach bunt	Ila
4180446	ProSet Discifix® C	Ila
4180447	ProSet Discifix® C	Ila
4180448	ProSet Discifix® C	Ila
4180449	ProSet Discifix® C	Ila
4180450	ProSet Discifix® C	Ila
4180451	ProSet Discifix® C	Ila
4180452	ProSet Discifix® C	Ila
4180454	ProSet Discifix® C	Ila
4180455	ProSet Discifix® C	Ila
4180456	ProSet Discifix® C	Ila
4180457	ProSet Discifix® C	Ila
4180458	ProSet Discifix® C	Ila
4180459	ProSet Discifix® C	Ila
4180460	ProSet Discifix® C	Ila
4180462	ProSet Discifix® C	Ila
4180463	ProSet Discifix® C	Ila
4180464	ProSet Discifix® C	Ila
4180465	ProSet Discifix® C	Ila
4180466	ProSet Discifix® C	Ila
4180467	ProSet Discifix® C	Ila
4180468	ProSet Discifix® C	Ila
4180469	ProSet Discifix® C	Ila
4180471	ProSet Discifix® C	Ila
4180472	ProSet Discifix® C	Ila
4180473	ProSet Discifix® C	Ila
4180474	ProSet Discifix® C	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4180475	ProSet Discifix® C	Ila
4180476	ProSet Discifix® C	Ila
4180477	ProSet Discifix® C	Ila
4180478	ProSet Discifix® C	Ila
4180479	ProSet Discifix® C	Ila
4180480	ProSet Discifix® C	Ila
4180481	ProSet Discifix® C	Ila
4180482	ProSet Discifix® C	Ila
4180483	ProSet Discifix® C	Ila
4180488	ProSet Infusions-Set	Ila
4180677	ProSet Discifix®C Hahnbank-Set 11-fach	Ila
4180678	ProSet Discifix® C Hahnbank-Set 8-fach	Ila
4180679	ProSet Discifix® C Hahnbank-Set 3-fach	Ila
4180965	ProSet Discifix®-Hahnbank-Set 5-fach	Ila
4181027	ProSet Discifix® C Hahnbank-Set 3-fach bunt	Ila
4181028	ProSet Discifix®C Hahnbank-Set 3-fach bunt	Ila
4181232	ProSet Discifix®C Hahnbank-Set 3-fach	Ila
4181360	ProSet Infusions-Wechselset	Ila
4181778	ProSet Discifix® C-Hahnbank-Set 5-fach	Ila
4181905	ProSet Discifix® C Hahnbank-Set 3-fach bunt	Ila
4182040	ProSet Discifix®-Hahnbank-Set 5-fach	Ila
4182181	ProSet Intrafix® SafeSet	Ila
4182182	ProSet Infusions-Set	Ila
4182190SP	ProSet Discifix®C-Hahnbank-Set 3-fach	Ila
4182308	ProSet Discifix®C Hahnbank-Set 5-fach	Ila
4182398	ProSet Discifix® C-Hahnbank Set 5-fach	Ila
4182399	ProSet Discifix® C Hahnbank-Set 3-fach	Ila
4182488	ProSet Discifix® C-Hahnbank Set 5-fach	Ila
4182490	ProSet Discifix®C-Hahnbank-Set 5-fach	Ila
4182502	ProSet High-Flow Dreiweg weiß	Ila
4182556	ProSet Infusions-Set	Ila
4182563	ProSet Discifix® C	Ila
4182564	ProSet Discifix® C	Ila
4182565	ProSet Discifix® C	Ila
4182566	ProSet Discifix® C	Ila
4182567	ProSet Discifix® C	Ila
4182568	ProSet Discifix® C	Ila
4182569	ProSet Discifix® C	Ila
4182633	ProSet Discifix® C Hahnbank-Set 3-fach bunt	Ila
4182635	ProSet Discifix® C Hahnbank-Set 5-fach bunt	Ila
4182638	ProSet Discifix®C Hahnbank-Set 3-fach bunt	Ila
4182639	ProSet Discifix® C Hahnbank-Set 3-fach bunt	Ila
4182651	ProSet Discifix® C-Hahnbank-Set	Ila
4182652	ProSet Discifix® C Hahnbank-Set	Ila
4182719	ProSet Discifix® C Hahnbank-Set 3-fach blau	Ila
4182720	ProSet Discifix®C Hahnbank-Set 3-fach bunt	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4182737	ProSet Discifix® C-Hahnbank-Set 5-fach	Ila
4182944	ProSet Discifix® C Hahnbank-Set 5-fach bunt	Ila
4182952	ProSet Infusions-Set	Ila
4183088	ProSet Discifix® C Hahnbank-Set 5-fach	Ila
4183312	ProSet Discifix®C Hahnbank Set 3-fach	Ila
4183371	ProSet Discifix®C Hahnbank-Set 5-fach	Ila
4183510	ProSet Discifix®C Hahnbank-Set 3-fach bunt	Ila
4183719	ProSet Infusions-Set	Ila
4183777	ProSet Discifix®C-Hahnbank-Set 3-fach	Ila
4183787	ProSet Discifix®C-Hahnbank-Set 5-fach	Ila
4183852	ProSet Discifix® C-Hahnbank-Set 3-fach	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
4184022	ProSet Infusion Set	Ila
4184023	ProSet Infusion Set	Ila
4184024	ProSet Infusion Set	Ila
4184026	ProSet Infusion Set	Ila
4184027	ProSet Infusion Set	Ila
4184028	ProSet Infusion Set	Ila
4184029	ProSet Infusion Set	Ila
4184030	ProSet Infusion Set	Ila
4184031	ProSet Infusion Set	Ila
4184032	ProSet Infusion Set	Ila
4184034	ProSet Infusion Set	Ila
4184035	ProSet Infusion Set	Ila
4184036	ProSet Infusion Set	Ila
4184037	ProSet Infusion Set	Ila
4184038	ProSet Infusion Set	Ila
4184039	ProSet Infusion Set	Ila
4184040	ProSet Infusion Set	Ila
4184246	ProSet Discifix®-Hahnbank-Set 5-fach	Ila
4184327	ProSet Discifix® C Hahnbank-Set 5-fach bunt	Ila
4184360	ProSet Infusions-Set	Ila
4184440	ProSet Hahnbank-Set 3 B	Ila
4184459	Infusions-Set	Ila
4184483	ProSet Discifix® C Hahnbank-Set 5-fach	Ila
4184491	ProSet Discifix® C Hahnbank-Set 5-fach blau	Ila
4184521	ProSet Discifix®C Hahnbank-Set 3A	Ila
4184549	ProSet Discifix®C Hahnbank Set 3-fach	Ila
4184817	ProSet Discifix®C Hahnbank-Set 3-fach bunt	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4184963	ProSet Discifix®-Hahnbank-Set 3-fach	Ila
4185021	ProSet Discifix®C Hahnbank Set 5-fach	Ila
4185366	ProSet Discifix®C Hahnbank Set 3-fach	Ila
4185447	ProSet Discifix®C Hahnbank-Set 3-fach bunt	Ila
4185448	PROSET WCS Discifix®C Hahnbank-Set	Ila
4185449	ProSet Discifix®C Hahnbank-Set 3-fach	Ila
4185450	ProSet Discifix® C	Ila
4185451	ProSet Discifix® C	Ila
4185452	ProSet Discifix® C	Ila
4185453	ProSet Discifix® C	Ila
4185454	ProSet Discifix® C	Ila
4185456	ProSet Discifix® C	Ila
4185457	ProSet Discifix® C	Ila
4185458	ProSet Discifix® C	Ila
4185459	ProSet Discifix® C	Ila
4185460	ProSet Discifix® C	Ila
4185461	ProSet Discifix® C	Ila
4185462	ProSet Discifix® C	Ila
4185510	ProSet Discifix®-Hahnbank-Set 3-fach	Ila
4185579	ProSet Infusions-Set	Ila
4185687	ProSet Infusions-Set	Ila
4185821N	ProSet Discifix®C Hahnbank 5-fach Set	Ila
4185875	ProSet Infusions-Set	Ila
4185927	ProSet Discifix® C-Hahnbank Set 5-fach	Ila
4185928	ProSet Discifix® C Hahnbank-Set 3-fach blau	Ila
4185972	ProSet Discifix®C Hahnbank Set 5-fach	Ila
4185985	ProSet Discifix®C Hahnbank-Set 3-fach bunt	Ila
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 WCS Discifix®C Hahnbank-Set	Ila
4186925	ProSet Discifix®C Dreiwegehahn Set gelb	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
4187205	ProSet Discifix® C	Ila
4187206	ProSet Discifix® C	Ila
4187207	ProSet Discifix® C	Ila
4187208	ProSet Discifix® C	Ila
4187209	ProSet Discifix® C	Ila
4187211	ProSet Discifix® C	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4187213	ProSet Discifix® C	Ila
4187214	ProSet Discifix® C	Ila
4187215	ProSet Discifix® C	Ila
4187216	ProSet Discifix® C	Ila
4187217	ProSet Discifix® C	Ila
4187218	ProSet Discifix® C	Ila
4187219	ProSet Discifix® C	Ila
4187220	ProSet Discifix® C	Ila
4187221	ProSet Discifix® C	Ila
4187222	ProSet Discifix® C	Ila
4187223	ProSet Discifix® C	Ila
4187224	ProSet Discifix® C	Ila
4187225	ProSet Discifix® C	Ila
4187226	ProSet Discifix® C	Ila
4187227	ProSet Discifix® C	Ila
4187228	ProSet Discifix® C	Ila
4187231	ProSet Discifix® C	Ila
4187233	ProSet Discifix® C	Ila
4187234	ProSet Discifix® C	Ila
4187235	ProSet Discifix® C	Ila
4187290	ProSet Discifix® C Hahnbank 3x5-fach Set	Ila
4187291	ProSet Discifix® C Hahnbank 9-fach Set	Ila
4187292	ProSet Discifix® C	Ila
4187293	ProSet Discifix® C	Ila
4187294	ProSet Discifix® C	Ila
4187295	ProSet Discifix® C	Ila
4187297	ProSet Discifix® C	Ila
4187298	ProSet Discifix® C	Ila
4187299	ProSet Discifix® C	Ila
4187301	ProSet Discifix® C	Ila
4187302	ProSet Discifix® C	Ila
4187303	ProSet Discifix® C	Ila
4187304	ProSet Discifix® C	Ila
4187305	ProSet Discifix® C	Ila
4187306	ProSet Discifix® C	Ila
4187307	ProSet Discifix® C	Ila
4187308	ProSet Discifix® C	Ila
4187309	ProSet Discifix® C	Ila
4187310	ProSet Discifix® C	Ila
4187311	ProSet Discifix® C	Ila
4187312	ProSet Discifix® C	Ila
4187313	ProSet Discifix® C	Ila
4187314	ProSet Discifix® C	Ila
4187315	ProSet Discifix® C	Ila
4187316	ProSet Discifix® C	Ila
4187317	ProSet Discifix® C	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4187319	ProSet Discifix® C	Ila
4187321	ProSet Discifix® C	Ila
4187322	ProSet Discifix® C	Ila
4187323	ProSet Discifix® C	Ila
4187324	ProSet Discifix® C	Ila
4187325	ProSet Discifix® C	Ila
4187327	ProSet Discifix® C	Ila
4187330	ProSet Discifix®C Hahnbank-Set	Ila
4187331	ProSet Discifix®C Hahnbank-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
4187529	ProSet Discifix®C Hahnbank-Set 5-fach bunt	Ila
4187750	ProSet Infusions-Set	Ila
4187823	ProSet Infusions-Set	Ila
4187826	ProSet Discifix®-Hahnbank-Set 5-fach	Ila
4187834	ProSet Discifix® C-Hahnbank-Set 3-fach	Ila
4187838	ProSet Discifix® C Hahnbank-Set 5-fach bunt	Ila
4187878	ProSet Discifix® C-Hahnbank-Set 5-fach	Ila
4187879	ProSet Discifix® C-Hahnbank-Set 3-fach	Ila
4187880	ProSet Discifix® C Hahnbank Set 3-fach	Ila
4187884	ProSet Discifix® C 3-fach (10 Stück)	Ila
4187898	ProSet Discifix®C Dreivegehahn Set	Ila
4187911	ProSet Discifix® C-Dreivegehahn Set	Ila
4187913	ProSet Discifix® C-Dreivegehahn Set	Ila
4187954	ProSet Discifix®-Hahnbank-Set 5-fach	Ila
4188004	ProSet Discifix®C Hahnbank-Set 3-fach	Ila
4188047	ProSet Discifix® C	Ila
4188071	ProSet Discifix®-Hahnbank Set 8-fach	Ila
4188072	ProSet Discifix®C Hahnbank-Set 3/3-fach	Ila
4188080	ProSet Infusions-Set	Ila
4188105	ProSet Discifix® Hahnbank Set 5-fach	Ila
4188109	ProSet Intrafix® SafeSet	Ila
4188188	ProSet Discifix® C-Hahnbank-Set 5-fach	Ila
4188189	ProSet Discifix® C-Hahnbank-Set 5-fach	Ila
4188198	ProSet Discifix®C-Hahnbank-Set 3-fach	Ila
4188225	ProSet Discifix®C Hahnbank-Set	Ila
4188510	ProSet Discifix® C Hahnbank Set 3-fach	Ila
4188957	ProSet Discifix®-Hahnbank-Set 6-fach	Ila
4188958	ProSet Discifix®C Hahnbank-Set 8-fach	Ila
4188959	ProSet Discifix®-Hahnbank-Set 3-fach	Ila
4188960	ProSet Discifix®-Hahnbank- Set 3-fach	Ila
4189821	ProSet Discifix® C Hahnbank-Set 5-fach bunt	Ila
4189839	ProSet Discifix® C Hahnbank-Set 5-fach blau	Ila



<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4189847	ProSet Discofix® C Hahnbank-Set 5-fach blau	Ila
4890078	ProSet Pumpenfüll-Set	Ila

**Amendment Information**

<b>Version</b>	<b>Description of changes</b>
50.0	Delete art. no. 4180631SP will be covered by DoC 39.05.018KIT
51.0	Change product name of art. no. 4186580 from "ProSet Discofix®C Hahnbank-Set" to "ProSet WCS Discofix®C Hahnbank-Set" Delete out of market art. no. 4089871, 4092996, 4187831, 4187865
52.0	Delete art. no. 4088549, 4186711, 4186950, 4186097, 4186110, 4186980, 4187011, 4188113, 4188116, 4188138, 4189109, 4187008, 4187010 which will be covered by 39.05.005KIT
53.0	Add art. no. 4188198, 4184549, 4187529, 4182490, 4187880, 4181028, 4180120, 4182638, formerly covered by 39.05.008KIT
54.0	Add art. no. 4187330 and 4187331

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, 19 May 2021, 08:18 W. Europe Daylight Time  
Meaning: Document signed as Author

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UserName: Henke, Gudrun (henkgude)  
Title: HC-RA Senior Manager Medical Devices CoE IVS  
Date: Wednesday, 19 May 2021, 18:29 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: Wednesday, 19 May 2021, 20:55 W. Europe Daylight Time  
Meaning: Approve Document

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