

**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**Urecath, Urecath Set,  
Ureter-Katheter-Set  
Dirocath®**Ureter-Katheter-Bestecke  
(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 0123**Datum der ersten CE-Kennzeichnung**  
1994-12**Gültig bis**  
2024-05-26hereby declare in our own responsibility  
that the product/s**Urecath, Urecath Set,  
Ureter-Katheter-Set  
Dirocath®**Ureter Catheter Sets  
(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14 June 1993  
concerning Medical Devices,  
amended by Directive 2007/47/EG**Conformity assessment procedure**  
according to annex II (excluding section 4)  
of the Directive named above**Classification**  
according to annex IX of the 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

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Page: Page: 2 of 3 2 of 3

Melsungen, 2020-01-08

i. V. 

Thomas Stefan Brand  
Vice President Quality Management  
for non-active Medical Devices

Melsungen, 2020-01-08

i. V.



Dr. Hans-Ulrich Gaudin  
Head of Global Regulatory Affairs  
OPM Germany

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Page: 3 of 3

Page:

3 of 3

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product Name</b>	<b>Klasse / Class</b>
4437497	Urecath	IIa
4437500	Urecath	IIa
4437535	Urecath	IIa
4437543	Urecath	IIa
4430921	Urecath Set	IIa
4430930	Urecath Set	IIa
4430948	Urecath Set	IIa
4430956	Urecath Set	IIa
4431057	Urecath Set	IIa
4431073	Urecath Set	IIa
4431081	Urecath Set	IIa
4431090	Urecath Set	IIa
4431103	Urecath Set	IIa
4431111	Urecath Set	IIa
4431120	Urecath Set	IIa
4431138	Urecath Set	IIa
4431200	Urecath Set	IIa
4431219	Urecath Set	IIa
4431227	Urecath Set	IIa
4431316	Urecath Set	IIa
4431600	Urecath Set	IIa
4431618	Urecath Set	IIa
4431626	Urecath Set	IIa
4432002	Urecath Set	IIa
4432010	Urecath Set	IIa
4432029	Urecath Set	IIa
4432690	Ureter-Katheter-Set	IIa
4432703	Ureter-Katheter-Set	IIa
4432711	Ureter-Katheter-Set	IIa
4432800	Ureter-Katheter-Set	IIa
4430530	Dirocath®	IIa
4430549	Dirocath®	IIa
4430646	Dirocath®	IIa
4431561	Urecath Set	IIa

Effective