

**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**PureSite - Closed Male Connector**
Transfervorrichtung zur Beimischung und
Verabreichung**PureSite - Dust Cover Cap**
Staubschutzkappe für PureSite

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni
1993über Medizinprodukte
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**
nach Anhang VII und V
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse I steril**Benannte Stelle**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**
2013-04**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**PureSite - Closed Male Connector**
Transfer-device for admixture and administration**PureSite - Dust Cover Cap**
Dust Cover Cap for PureSite

(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June
1993concerning Medical Devices
amended by Directive 2007/47/EC**Conformity Assessment Procedure**
according to annex VII and V
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class I sterile**Notified Body**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123**Date of first CE-marking**
2013-04**Valid until**
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4551100	PureSite - Closed Male Connector	I steril / I sterile
4551101	PureSite - Dust Cover Cap	I steril / I sterile
4551102	PureSite - Closed Male Connector	I steril / I sterile
4551103	PureSite - Dust Cover Cap	I steril / I sterile
4551104	PureSite - Closed Male Connector	I steril / I sterile
4551105	PureSite - Closed Male Connector	I steril / I sterile

Amendment Information

Version	Description of the changes
05	Add art. no. 4551104, 4551105
06	Update validity

Title: Declaration of Conformity - 214-013 - PureSite Initiator: Caroline ? Herbst

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

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Meaning: Document signed as Author
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