

**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**Sterifix® 0.2 µm**
0,2 µm Injektionsfilter**Sterifix® Filter Straw**
Filterhalme**Sterifix® Filter Needle**
Filternadeln**Sterifix® Pury**
5 µm Injektionsfilter

(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**
1994-12**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**Sterifix® 0.2 µm**
0.2 µm Injection Filter**Sterifix® Filter Straw**
Filter Straws**Sterifix® Filter Needle**
Filter Needles**Sterifix® Pury**
5 µm Injection Filter

(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**
1994-12**Valid until**
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4099206	Sterifix® 0.2 µm	I steril / I sterile
4550200	Sterifix® Filter Straw	I steril / I sterile
4550200N	Sterifix® Filter Straw	I steril / I sterile
4550250	Sterifix® Filter Straw	I steril / I sterile
4550250N	Sterifix® Filter Straw	I steril / I sterile
4550404	Sterifix® Filter Needle	I steril / I sterile
4550404N	Sterifix® Filter Needle	I steril / I sterile
4550420	Sterifix® Filter Needle	I steril / I sterile
4551001	Sterifix® Pury	I steril / I sterile

Amendment Information

Version	Description of the changes
10	Add art. no. 4550250N, 4550200N, 4550404N
11	Update validity

Title: Declaration of Conformity - 39.05.010 - Sterifix Injection Filter 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: Monday, 30 March 2020, 11:48 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Seidel, Stefan (seidstde)
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems
Date: Monday, 30 March 2020, 14:17 W. Europe Daylight Time
Meaning: Approve Document

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Monday, 30 March 2020, 19:08 W. Europe Daylight Time
Meaning: Approve Document
