

**Konformitätserklärung
Declaration of Conformity**

Wir

**B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany**

We

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/übereinstimmen

Richtlinie 93/42/EWG des Rates vom 14. Juni
1993

über 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
2024-05-26

hereby 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
1993

concerning 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:

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Date: Monday, 30 March 2020, 19:08 W. Europe Daylight Time
Meaning: Approve Document
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