

**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**Sterican® Safety Needle**

Hypodermische Sicherheitskanüle

(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 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**
2018-03**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**Sterican® Safety Needle**

Safety Hypodermic Needle

(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 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**
2018-03**Valid until**
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4670002S-01	Sterican® Safety Needle	Ila
4670005S-01	Sterican® Safety Needle	Ila
4670008S-01	Sterican® Safety Needle	Ila
4670008SBR	Sterican® Safety Needle	Ila
4670012S-01	Sterican® Safety Needle	Ila
4670016S-01	Sterican® Safety Needle	Ila
4670020S-01	Sterican® Safety Needle	Ila
4670022S-01	Sterican® Safety Needle	Ila
4670025S-01	Sterican® Safety Needle	Ila
4670027S-01	Sterican® Safety Needle	Ila
4670028S-01	Sterican® Safety Needle	Ila
4670030S-01	Sterican® Safety Needle	Ila
4670030SBR	Sterican® Safety Needle	Ila
4670032S-01	Sterican® Safety Needle	Ila
4670035S-01	Sterican® Safety Needle	Ila
4670035SBR	Sterican® Safety Needle	Ila
4670040S-01	Sterican® Safety Needle	Ila
4670040SBR	Sterican® Safety Needle	Ila
4670042S-01	Sterican® Safety Needle	Ila
4670045S-01	Sterican® Safety Needle	Ila
4670045SBR	Sterican® Safety Needle	Ila
4670047S-01	Sterican® Safety Needle	Ila
4670050S-01	Sterican® Safety Needle	Ila
4670052S-01	Sterican® Safety Needle	Ila
4670053S-01	Sterican® Safety Needle	Ila
4670053SBR	Sterican® Safety Needle	Ila
4670055S-01	Sterican® Safety Needle	Ila
4670055SBR	Sterican® Safety Needle	Ila

Amendment Information

Version	Description of the changes
01	Initial creation of document
02	Add art. no. 4670008SBR, 4670030SBR, 4670035SBR, 4670040SBR, 4670045SBR, 4670053SBR, 4670055SBR

Title: Declaration of Conformity -DC-098-100 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, 17 June 2019, 08:09 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Brand, Thomas (brantode)
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Date: Tuesday, 18 June 2019, 08:32 W. Europe Daylight Time
Meaning: Approve Document
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Meaning: Approve Document
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