

Konformitätserklärung Declaration of Conformity

Wir

We

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201

erklären in eigener Verantwortung,
dass das/die Produkt/e

hereby declare in our own responsibility
that the product/s

Sterican® Safety Needle
Hypodermische Sicherheitskanüle

Sterican® Safety Needle
Safety Hypodermic Needle

(Artikelnummern und Basic UDI-DI siehe Anlage I)

(article numbers and Basic UDI-DI see attachment I)

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745
übereinstimmt/übereinstimmen

is/are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

Conformity Assessment Procedure
according to annex IX
of the Regulation named above

Klassifizierung
gemäß Anhang VIII der oben genannten
Verordnung
Klasse IIa

Classification
according to annex VIII of the Regulation named
above
Class IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Gültig bis
gemäß gültigem EU Zertifikat
(Nr. G10 012974 0611)

Valid until
according to our valid EU Certificate
(No. G10 012974 0611)

Anlage I / Attachment I**Basic UDI-DI: 403923900000076936**

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
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
4670032S-01	Sterican® Safety Needle	Ila
4670035S-01	Sterican® Safety Needle	Ila
4670040S-01	Sterican® Safety Needle	Ila
4670042S-01	Sterican® Safety Needle	Ila
4670045S-01	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
4670055S-01	Sterican® Safety Needle	Ila
---	European Labelling (-01 / EU)	---
4670008SBR	Sterican® Safety Needle	Ila
4670030SBR	Sterican® Safety Needle	Ila
4670035SBR	Sterican® Safety Needle	Ila
4670040SBR	Sterican® Safety Needle	Ila
4670045SBR	Sterican® Safety Needle	Ila
4670053SBR	Sterican® Safety Needle	Ila
4670055SBR	Sterican® Safety Needle	Ila
	Brazil Labelling (BR)	
4670006S-01	Sterican® Safety Needle	Ila
4670056S-01	Sterican® Safety Needle	Ila
4670059S-01	Sterican® Safety Needle	Ila
4670058S-01	Sterican® Safety Needle	Ila
4670057S-01	Sterican® Safety Needle	Ila
	Portfolio extension less than 2 inch	
4670029S-01	Sterican® Safety Needle	Ila
	Portfolio extension 9mm	

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4670060S-01	Sterican® Safety Needle	Ila
4670061S-01	Sterican® Safety Needle	Ila
4670062S-01	Sterican® Safety Needle	Ila
4670063S-01	Sterican® Safety Needle	Ila
4670064S-01	Sterican® Safety Needle	Ila
	Portfolio extension 2 inch	

Document amendment information

Version	Description of the changes
2.0	Portfolio extension 2 inch; project F.101-0407.001-03; article codes: 4670060S-01, 4670061S-01, 4670062S-01, 4670063S-01, 4670064S-01
1.0	Initial Version

Title: Declaration of Conformity 098-100 - Sterican Safety Needle - MDR Initiator: Ulrich ? Jedelhauser

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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UserName: Brand, Thomas Stefan (brantode)

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Date: Thursday, 02 October 2025, 12:44 W. Europe Daylight Time

Meaning: Approve Document

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UserName: Seidel, Stefan (seidstde)

Title: Vice President Regulatory Affairs CoE Infusion & Pain Therapy

Date: Thursday, 02 October 2025, 17:21 W. Europe Daylight Time

Meaning: Approve Document

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