

## 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: 40392390000076936**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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	

**Document amendment information**

Version	Description of the changes
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:

UserName: Jedelhauser, Ulrich (jedeulde)  
Title: Senior Manager Regulatory Affairs CoE Infusion & Pain Therapy  
Date: Thursday, 02 May 2024, 13:30 W. Europe Daylight Time  
Meaning: Document signed as Author

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UserName: Brand, Thomas (brantode)  
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices  
Date: Thursday, 02 May 2024, 14:13 W. Europe Daylight Time  
Meaning: Approve Document

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UserName: Seidel, Stefan (seidstde)  
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy  
Date: Thursday, 02 May 2024, 15:09 W. Europe Daylight Time  
Meaning: Approve Document

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