

**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**Sterican®**
Einmalkanülen

(Artikelnummern und Basic UDI-DI siehe Anlage I)

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745
übereinstimmt/übereinstimmen**Konformitätsbewertungsverfahren**
nach Anhang IX
der oben genannten Verordnung**Klassifizierung**
gemäß Anhang VIII der oben genannten
Verordnung
Klasse IIa**Benannte Stelle**
TÜV SÜD Product Service GmbH
Kennnummer 0123**Gültig bis**
gemäß gültigem EU Zertifikat
(Nr. G10 012974 0611)hereby declare in our own responsibility
that the product/s**Sterican®**
Hypodermic Needles for Single Use

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

is/are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745**Conformity Assessment Procedure**
according to annex IX
of the Regulation named above**Classification**
according to annex VIII of the Regulation named
above
Class IIa**Notified Body**
TÜV SÜD Product Service GmbH
Identification number 0123**Valid until**
according to our valid EU Certificate
(No. G10 012974 0611)

Anlage I / Attachment I**Basic UDI-DI: 40392390000076834**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4650018	Sterican®	Ila
4650034	Sterican®	Ila
4657500	Sterican®	Ila
4657519	Sterican®	Ila
4657527	Sterican®	Ila
4657543	Sterican®	Ila
4657624	Sterican®	Ila
4657640	Sterican®	Ila
4657667	Sterican®	Ila
4657675	Sterican®	Ila
4657683	Sterican®	Ila
4657705	Sterican®	Ila
4657799	Sterican®	Ila
4657853	Sterican®	Ila
4660021	Sterican®	Ila
4665112	Sterican®	Ila
4665120	Sterican®	Ila
4665317	Sterican®	Ila
4665406	Sterican®	Ila
4665457	Sterican®	Ila
4665465	Sterican®	Ila
4665503	Sterican®	Ila
4665511	Sterican®	Ila
4665600	Sterican®	Ila
4665635	Sterican®	Ila
4665643	Sterican®	Ila
4665791	Sterican®	Ila
4667093	Sterican®	Ila
4667123	Sterican®	Ila
9180109	Sterican®	Ila
9180117	Sterican®	Ila
9186158	Sterican®	Ila
9186166	Sterican®	Ila
9186174	Sterican®	Ila
9186182	Sterican®	Ila

Document amendment information

Version	Description of the changes
1.0	Initial Version

Title: Declaration of Conformity 098-001 - Sterican - 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: Wednesday, 15 May 2024, 10:46 W. Europe Daylight Time
Meaning: Document signed as Author

=====

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 15 May 2024, 11:49 W. Europe Daylight Time
Meaning: Approve Document

=====

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Wednesday, 15 May 2024, 16:42 W. Europe Daylight Time
Meaning: Approve Document

=====