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® MIX
Stumpfe Kanüle für die Medikamentenzumischung

Sterican® MIX
Blunted needle for drug admixture

(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 I steril

Classification
according to annex VIII of the Regulation named above
Class I sterile

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. G11 12974 0626)

Valid until
according to our valid EU Certificate
(Nr. G11 12974 0626)

Effective

Anlage I / Attachment I

Basic UDI-DI: 403923900000025726

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4038088-01	Sterican® MIX	I steril / I sterile
4038088-03	Sterican® MIX	I steril / I sterile
4550400-01	Sterican® MIX	I steril / I sterile
4550400-03	Sterican® MIX	I steril / I sterile
4550400-04	Sterican® MIX	I steril / I sterile

Effective

Document amendment information

Version	Description of the changes
2.0	Correction of Classification from class IIa to class I sterile on front page; risk class in Anlage I / Attachment I is correct (I sterile)
1.0	Initial Version

Title: Declaration of Conformity 214-012 - Sterican MIX - 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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