

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 Produkt

Omnifix®

Spülspritzen steril

Basis UDI-DI: 40392390000029126
(Artikelnummern siehe Anlage I)

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

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

Klassifizierung

gemäß Anhang VIII der oben genannten
Verordnung
Klasse I steril Messfunktion

Benannte Stelle

TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis

gemäß gültigem EU Zertifikat
(No. G11 012974 0626)

hereby declare in our own responsibility
that the products

Omnifix®

Irrigation syringes sterile

Basic UDI-DI: 40392390000029126
(article numbers see attachment I)

is 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 I sterile measuring function

Notified Body

TÜV SÜD Product Service GmbH
Identification number 0123

Valid until

according to our valid EU Certificate
(No. G11 012974 0626)

Anlage I / Attachment I**Basic UDI-DI: 40392390000029126**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4613503F	Omnifix®	I steril Messfunktion / I sterile measuring function

Document amendment information

Version	Description of the changes
1.0	Initial Version under 2017/745 MDR

Title: Declaration of Conformity - 094-003-MDR - Irrigation Syringes Initiator: Julia2 ? Mueller

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Mueller, Julia2 (hampjude)
Title: Senior Manager Regulatory Affairs CoE Infusion & Pain Therapy
Date: Thursday, 23 May 2024, 08:36 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Thursday, 23 May 2024, 10:18 W. Europe Daylight Time
Meaning: Approve Document

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Thursday, 23 May 2024, 10:49 W. Europe Daylight Time
Meaning: Approve Document
