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 die Produkte

Omnifix® Luer Solo
Omnifix®-F Luer Solo
3-piece Single-use Syringe with Luer connector without needle Type Solo
Basis UDI-DI: 4039239000000261ZS
(Artikelnummern siehe Anlage I)

Omnifix®-H Luer Solo
3-piece Single-use Syringe with Luer connector with Heparin scale without needle Type Solo
Basis UDI-DI: 4039239000000263ZW
(Artikelnummern siehe Anlage I)

Omnifix® Luer Lock Solo
Omnifix®-F Luer Lock Solo
3-piece Single-use Syringe with Luer Lock connector without needle Type Solo
Basis UDI-DI: 4039239000000262ZU
(Artikelnummern siehe Anlage I)

Omnifix® Luer Lock Solo
3-piece Single-use Syringe with Luer Lock connector without needle Type Solo UV-Protect
Basic UDI-DI: 403923900000207022
(Artikelnummern siehe Anlage I)

Omnifix® 40 Solo
Omnifix® 100 Solo
3-piece Single-use Syringe with Luer connector without needle with Insulin scale Type Solo
Basis UDI-DI: 403923900000121925
(Artikelnummern siehe Anlage I)

hereby declare in our own responsibility that the products

Omnifix® Luer Solo
Omnifix®-F Luer Solo
3-piece Single-use Syringe with Luer connector without needle Type Solo
Basic UDI-DI: 4039239000000261ZS
(article numbers see attachment I)

Omnifix®-H Luer Solo
3-piece Single-use Syringe with Luer connector with Heparin scale without needle Type Solo
Basic UDI-DI: 4039239000000263ZW
(article numbers see attachment I)

Omnifix® Luer Lock Solo
Omnifix®-F Luer Lock Solo
3-piece Single-use Syringe with Luer Lock connector without needle Type Solo
Basic UDI-DI: 4039239000000262ZU
(article numbers see attachment I)

Omnifix® Luer Lock Solo
3-piece Single-use Syringe with Luer Lock connector without needle Type Solo UV-Protect
Basic UDI-DI: 403923900000207022
(article numbers see attachment I)

Omnifix® 40 Solo
Omnifix® 100 Solo
3-piece Single-use Syringe with Luer connector without needle with Insulin scale Type Solo
Basic UDI-DI: 403923900000121925
(article numbers see attachment I)

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Omnifix® Luer Duo
Omnifix®-F Luer Duo
3-piece Single-use Syringe with Luer connector with needle Type Duo
Basis UDI-DI: 403923900000077633
(Artikelnummern siehe Anlage I)

Omnifix® Luer Lock Solo
3-piece Single-use Syringe with Luer Lock connector without needle Type Solo
Basis UDI-DI: 403923900000077735
(Artikelnummern siehe Anlage I)

Omnifix® 40 Duo
Omnifix® 100 Duo
3-piece Single-use Syringe with Luer connector with needle with Insulin scale Type Duo
Basis UDI-DI: 4039239000001217ZW
(Artikelnummern siehe Anlage I)

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

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

Klassifizierung
gemäß Anhang VIII der oben genannten Verordnung
Klasse I steril Messfunktion
oder
Klasse IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis
gemäß gültiger EU Zertifikate
Nr. G11 012974 0626 (Klasse I steril Messfunktion)
oder
Nr. G10 012974 0611 (Klasse IIa)

Omnifix® Luer Duo
Omnifix®-F Luer Duo
3-piece Single-use Syringe with Luer connector with needle Type Duo
Basic UDI-DI: 403923900000077633
(article numbers see attachment I)

Omnifix® Luer Lock Solo
3-piece Single-use Syringe with Luer Lock connector without needle Type Solo
Basic UDI-DI: 403923900000077735
(article numbers see attachment I)

Omnifix® 40 Duo
Omnifix® 100 Duo
3-piece Single-use Syringe with Luer connector with needle with Insulin scale Type Duo
Basic UDI-DI: 4039239000001217ZW
(article numbers see attachment I)

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 I sterile measuring function
or
Class IIa

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Valid until
according to our valid EU Certificates
No. G11 012974 0626 (class I sterile measuring function)
or
No. G10 012974 0611 (class IIa)

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Anlage I / Attachment I

Basic UDI-DI 4039239000000261ZS

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4616022V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616025V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616050V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616057V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616103V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616107V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616200V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616200V-03	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616308F	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
9161406V	Omnifix®-F Luer Solo	I steril Messfunktion / I sterile measuring function
4616502F	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
9167112V	Omnifix®-F Luer Solo	I steril Messfunktion / I sterile measuring function

Basic UDI-DI 4039239000000263ZW

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
9162607V	Omnifix®-H Luer Solo	I steril Messfunktion / I sterile measuring function
9162909V	Omnifix®-H Luer Solo	I steril Messfunktion / I sterile measuring function

Basic UDI-DI 4039239000000262ZU

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4617029LDS	Omnifix® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
9167006V	Omnifix®-F Luer Lock Solo	I steril Messfunktion / I sterile measuring function

Basic UDI-DI 403923900000121925

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
9161309V	Omnifix® 40 Solo	I steril Messfunktion / I sterile measuring function
9161708V	Omnifix® 100 Solo	I steril Messfunktion / I sterile measuring function

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Basic UDI-DI 403923900000077633

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4643011C	Omnifix® Luer Duo	IIa
4643100V	Omnifix® Luer Duo	IIa
4643102C	Omnifix® Luer Duo	IIa
4643102V	Omnifix® Luer Duo	IIa
4643105V	Omnifix® Luer Duo	IIa
4643119C	Omnifix® Luer Duo	IIa
4643119V	Omnifix® Luer Duo	IIa
4643127C	Omnifix® Luer Duo	IIa
4643127V	Omnifix® Luer Duo	IIa
4643135C	Omnifix® Luer Duo	IIa
4643135V	Omnifix® Luer Duo	IIa
4643161	Omnifix® Luer Duo	IIa
9161465V	Omnifix®-F Luer Duo	IIa

Basic UDI-DI 403923900000077735

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4617022V	Omnifix® Luer Lock Solo	IIa
4617022V-03	Omnifix® Luer Lock Solo	IIa
4617029V	Omnifix® Luer Lock Solo	IIa
4617053V	Omnifix® Luer Lock Solo	IIa
4617053V-03	Omnifix® Luer Lock Solo	IIa
4617100CA	Omnifix® Luer Lock Solo	IIa
4617100V	Omnifix® Luer Lock Solo	IIa
4617100V-03	Omnifix® Luer Lock Solo	IIa
4617207V	Omnifix® Luer Lock Solo	IIa
4617207V-03	Omnifix® Luer Lock Solo	IIa
4617304F	Omnifix® Luer Lock Solo	IIa
4617509F	Omnifix® Luer Lock Solo	IIa
4617509F-03	Omnifix® Luer Lock Solo	IIa

Basic UDI-DI 403923900000207022

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4617510F-06	Omnifix® Luer Lock Solo	IIa

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Basic UDI-DI 4039239000001217ZW

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
9161333V	Omnifix® 40 Duo	IIa
9161376C	Omnifix® 100 Duo	IIa
9161376V	Omnifix® 100 Duo	IIa

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Document amendment information

Version	Description of the changes
1.0	Initial Version under Medical Device Regulation (EU) 2017/745.
2.0	Addition of article codes 4616502F, 4617509F and 4617509F-03 Addition of BUDI 403923900000207022 with article code 4617510F-06
3.0	Addition of article code 9167112V

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Title: Declaration of Conformity - 094-001 - MDR - Omnifix Initiator: Julia ? Mueller

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

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Date: Monday, 09 December 2024, 10:06 W. Europe Daylight Time
Meaning: Approve Document
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