

**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  
Basis UDI-DI: 403923900000020702  
(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: 4039239000000121925  
(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  
Basis UDI-DI: 403923900000020702  
(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: 4039239000000121925  
(article numbers see attachment I)

**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)

**Anlage I / Attachment I****Basic UDI-DI 4039239000000261ZS**

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

**Basic UDI-DI 4039239000000263ZW**

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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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 4039239000000121925**

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

**Basic UDI-DI 403923900000077633**

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

**Basic UDI-DI 403923900000077735**

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

**Basic UDI-DI 4039239000000207022**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4617510F-06	Omnifix® Luer Lock Solo	Ila

**Basic UDI-DI 4039239000001217ZW**

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

Effective

**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

Title: Declaration of Conformity - 094-001 - MDR - Omnifix Initiator: Julia2 ? Mueller

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

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