

**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: 4039239000000207022  
(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: 4039239000000207022  
(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)

**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 403923900000261ZS**

| <b>Art.-Nr. /<br/>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 403923900000263ZW**

| <b>Art.-Nr. /<br/>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 403923900000262ZU**

| <b>Art.-Nr. /<br/>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 403923900000121925**

| <b>Art.-Nr. /<br/>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 40392390000077633**

| <b>Art.-Nr. /<br/>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 40392390000077735**

| <b>Art.-Nr. /<br/>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 403923900000207022**

| <b>Art.-Nr. /<br/>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. /<br/>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                   |

**Document amendment information**

| <b>Version</b> | <b>Description of the changes</b>   |
|----------------|---|
| <b>1.0</b>     | Initial Version under Medical Device Regulation (EU) 2017/745.  |
| <b>2.0</b>     | Addition of article codes 4616502F, 4617509F and 4617509F-03<br>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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