

**Konformitätserklärung  
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG  
Carl-Braun-Straße 1  
34212 Melsungen  
Deutschland/Germany**erklären in eigener Verantwortung,  
dass das/die Produkt/e**Solofix®**  
Lanzette, Blut, steril

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie  
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni  
1993 über Medizinprodukte,  
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**  
nach Anhang II  
ohne Abschnitt 4  
der oben genannten Richtlinie**Klassifizierung**  
gemäß Anhang IX der oben genannten  
Richtlinie:  
Klasse IIa**Benannte Stelle**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Deutschland  
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**  
1997-04**Gültig bis**  
2024-05-26hereby declare in our own responsibility  
that the product/s**Solofix®**  
Lancets, blood, sterile

(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14 June 1993  
concerning Medical Devices,  
amended by Directive 2007/47/EG**Conformity assessment procedure**  
according to annex II  
without part 4  
of the Directive named above**Classification**  
according to annex IX of the Directive named  
above:  
Class IIa**Notified body**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Germany  
Identification number 0123**Date of first CE-marking**  
1997-04**Valid until**  
2024-05-26

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product Name</b>	<b>Klasse / Class</b>
6182003	Solofix®	Ila
6185002	Solofix®	Ila

**Amendment Information**

<b>Version</b>	<b>Description of the changes</b>
16	Annual revision acc. to TÜV audit 05-2009
17	Annual revision acc. to TÜV audit 05-2009 Version 1: BBMAG OPM; Version 2: BBMAG
18	Adaption to SOP HO-DDDD-M-5-2-05-715
19	Correction of conformity assessment procedure to “according to annex II without part 4”
20	Adaptation of validity to the MDR-deadline

Title: Declaration of Conformity - 084-003 - Solofix Initiator: Anna Heil

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

UserName: Heil, Anna (heilaade)  
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Meaning: Document signed as Author

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UserName: Moeller, Thomas (moelthde)  
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