

Konformitätserklärung Declaration of Conformity

Wir

We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201

erklären in eigener Verantwortung,
dass das Produkt

Perfusor® compact^{plus}
 Infusionsspritzenpumpe
 Basis UDI-DI: 403923900000038ZM
 (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 IIb

Benannte Stelle
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123

Des Weiteren erklären wir in eigener Verantwortung, dass oben genanntes Medizinprodukt die Anforderung zu folgenden EU Richtlinien

Richtlinie 2011/65/EU

des Europäischen Parlaments
und des Rates vom 8. Juni 2011
zur Beschränkung der Verwendung bestimmter
gefährlicher Stoffe in Elektro- und
Elektronikgeräten

hereby declare in our own responsibility
that the product

Perfusor® compact^{plus}
 Infusion syringe pump
 Basic UDI-DI: 403923900000038ZM
 (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 IIb

Notified Body
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123

Furthermore, we declare in our own responsibility that the above-mentioned medical device meets the requirements of the following EU Directives

Directive 2011/65/EU

of the European Parliament and
of the Council of 8th June 2011
on the restriction of the use of certain
hazardous substances in electrical and
electronic equipment—

B | BRAUN

- Conformity Declaration -
Declaration of Conformity -
164-005 - Perfusor
compactplus - MDR

B. Braun Melsungen AG
Automated Infusion Systems -
Regulatory Affairs **Effective**

Document No.: 164-005-MDR
Version: 2.0
Effective Date: 2022-02-08
Page: 2 of 5

und

Richtlinie 2006/42/EG

des Europäischen Parlaments und des Rates
vom 17. Mai 2006 über Maschinen und zur
Änderung der Richtlinie 95/16/EG (Neufassung)

erfüllt

Gültig bis
gemäß gültigem EU Zertifikat
G10 012974 0611

and

Directive 2006/42/EC

of the European Parliament and of the
Council of 17th May 2006 on machinery, and
amending Directive 95/16/EC (recast)

Valid until
according to our valid EU Certificate
G10 012974 0611

Effective



B | BRAUN

- Conformity Declaration -
Declaration of Conformity -
164-005 - Perfusor
compactplus - MDR

B. Braun Melsungen AG
Automated Infusion Systems -
Regulatory Affairs **Effective**

Document No.: 164-005-MDR
Version: 2.0
Effective Date: 2022-02-08
Page: 3 of 5

Anlage I / Attachment I

Basic UDI-DI 4039239000000038ZM

Art.-Nr. / Art. No.	Produktname / Product name
8717030	Perfusor® compact ^{plus}

Klasse / Class
IIB



Effective

Amendment Information

Version	Description of the changes
1.0	Initial version of document.
2.0	Stating of SRN and reference to valid EU Certificate in accordance with updated DoC Template



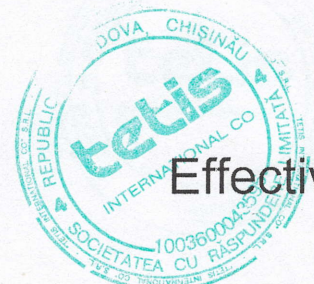
Title: Declaration of Conformity - 164-005 - Perfusor compactplus - MDR Initiator: Anna Heil

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

UserName: Heil, Anna (heilaade)
Title: Junior Manager Regulatory Affairs
Date: Monday, 07 February 2022, 07:39 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Heil, Juergen (heiljrde)
Title: VP Quality Management HC
Date: Monday, 07 February 2022, 11:08 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Grosser, Simone (donnside)
Title: Head of Regulatory Affairs CoE Pain Control & CVC
Date: Tuesday, 08 February 2022, 07:39 W. Europe Daylight Time
Meaning: Approve Document
=====

**Effective**