

**Konformitätserklärung
Declaration of Conformity**

Wir

We

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201erklären in eigener Verantwortung,
dass die Produkte**Cyto-Set® Infusion**Infusionsgerät. Nur für Schwerkräftinfusionen.
Basis UDI-DI: 403923900000026729**Cyto-Set® Infusomat® Space,
Cyto-Set® Infusomat® plus**Infusionsgerät für die Zytostatika-Applikation.
Für die Verwendung mit geeigneten
Druckinfusionsapparaten.
Basis UDI-DI: 40392390000007832Y**Cyto-Set® Line,
Cyto-Set® Mix**Verbindungssysteme zur Mischung und
Überleitung von Zytostatika
Basis UDI-DI: 403923900000078432**Cyto-Set® Pump Adapter**Adapter für die Applikation von Zytostatika zum
Anschluss an das Infusionsgerät. Zur Infusion
mit geeigneten Pumpen.
Basis UDI-DI: 403923900000078534

(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
Verordnunghereby declare in our own responsibility
that the products**Cyto-Set® Infusion**I.V. administration set. Only for gravity infusion.
Basic UDI-DI: 403923900000026729**Cyto-Set® Infusomat® Space,
Cyto-Set® Infusomat® plus**I.V. administration set for the application of
cytostatics. For infusion by compatible pumps.

Basic UDI-DI: 40392390000007832Y

**Cyto-Set® Line,
Cyto-Set® Mix**Connection systems for mixing and supplying
cytostatics
Basic UDI-DI: 403923900000078432**Cyto-Set® Pump Adapter**Adapter for the application of cytostatics for
connection to I.V. administration set. For
infusion by compatible pumps.
Basic UDI-DI: 403923900000078534

(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

Klasse IIa
Klasse I steril

Benannte Stelle

TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis

gemäß unseren gültigen EU Zertifikaten
(Nr. G10 012974 0611 und
Nr. G11 012974 0626)

Class IIa
Class I sterile

Notified Body

TÜV SÜD Product Service GmbH
Identification number 0123

Valid until

according to our valid EU Certificates
(No. G10 012974 0611 and
No. G11 012974 0626)

Effective

Anlage I / Attachment I**Basic UDI-DI 403923900000026729**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
A1686SNF	Cyto-Set® Infusion	I steril / I sterile
A1687	Cyto-Set® Infusion	I steril / I sterile
A1687SNF	Cyto-Set® Infusion	I steril / I sterile
A1688	Cyto-Set® Infusion	I steril / I sterile

Basic UDI-DI 40392390000007832Y

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8250414SP	Cyto-Set® Infusomat® Space	Ila
8250817SP	Cyto-Set® Infusomat® Space	Ila
8250820SP	Cyto-Set® Infusomat® Space	Ila
8250917SP	Cyto-Set® Infusomat® Space	Ila
8250920SP	Cyto-Set® Infusomat® Space	Ila
835414SP	Cyto-Set® Infusomat® Space	Ila
835817SP	Cyto-Set® Infusomat® Space	Ila
835820SP	Cyto-Set® Infusomat® Space	Ila
835917SP	Cyto-Set® Infusomat® Space	Ila
835920SP	Cyto-Set® Infusomat® Space	Ila
8700420	Cyto-Set® Infusomat® Plus	Ila
8700430	Cyto-Set® Infusomat® Plus	Ila
8700440	Cyto-Set® Infusomat® Plus	Ila
8700450	Cyto-Set® Infusomat® Plus	Ila
8700460	Cyto-Set® Infusomat® Plus	Ila
8700470	Cyto-Set® Infusomat® Plus	Ila
8700480	Cyto-Set® Infusomat® Plus	Ila
8700490	Cyto-Set® Infusomat® Plus	Ila

Basic UDI-DI 40392390000007843Z

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
A2581NF	Cyto-Set® Line	Ila
A2582NF	Cyto-Set® Line	Ila

Basic UDI-DI 403923900000078432

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
A2900N	Cyto-Set® Mix	Ila
A2903N	Cyto-Set® Mix	Ila
A2906N	Cyto-Set® Mix	Ila
A2907N	Cyto-Set® Mix	Ila
A2908N	Cyto-Set® Mix	Ila

Basic UDI-DI 403923900000078534

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
A1673SO	Cyto-Set® Pump Adapter	Ila

Effective

Document amendment information

Version	Description of the changes
1.0	First issue under Medical Device Regulation (MDR)
2.0	Addition of Cyto-Set® Pump Adapter incl. Intended Purpose, Basic UDI-DI 403923900000078534 and art. no. A1673SO

Effective

Title: Declaration of Conformity - 106-001 - MDR - Cyto-Set Initiator: Meike ? Junius

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

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