

**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**Cyto-Set® Infusion**

Infusionsgerät. Nur für Schwerkraftinfusionen.

**Cyto-Set® Infusomat® Space,
Cyto-Set® Infusomat® plus**Infusionsgerät für die Zytostatika-Applikation.
Für die Verwendung mit geeigneten
Druckinfusionsapparaten.**Cyto-Set® Line,
Cyto-Set® Mix**Verbindungssysteme zur Mischung und
Überleitung von Zytostatika

(Artikelnummern und Basic UDI-DI 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 IIa
Klasse I steril**Benannte Stelle**TÜV SÜD Product Service GmbH
Kennnummer 0123**Gültig bis**

gemäß unseren gültigen EU Zertifikaten

hereby declare in our own responsibility
that the products**Cyto-Set® Infusion**

I.V. administration set. Only for gravity infusion.

**Cyto-Set® Infusomat® Space,
Cyto-Set® Infusomat® plus**I.V. administration set for the application of
cytostatics. For infusion by compatible pumps.**Cyto-Set® Line,
Cyto-Set® Mix**Connection systems for mixing and supplying
cytostatics

(article numbers and Basic UDI-DI 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 IIa
Class I sterile**Notified Body**TÜV SÜD Product Service GmbH
Identification number 0123**Valid until**

according to our valid EU Certificates

Effective

(Nr. G10 012974 0611 und
Nr. G11 012974 0626)

(No. G10 012974 0611 and
No. G11 012974 0626)

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

Document amendment information

Version	Description of the changes
1.0	First issue under Medical Device Regulation (MDR)

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

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