

**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**Cyto-Set® Infusion,
Cyto-Set® Infusomat® Space,
Cyto-Set® Infusomat® plus**
Infusionsgeräte für die intravenöse
Zytostatika-Applikation**Cyto-Set® Pump Adapter**
Spezial Adapter für die Zytostatika-Applikation
mit Druck**Cyto-Set® Line,
Cyto-Set® Mix**
Verbindungssysteme zur Mischung und
Überleitung von Zytostatika

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni
1993über Medizinprodukte
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**
nach Anhang II (ausgenommen Abschnitt 4)
nach Anhang VII und V)
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa
Klasse I sterilhereby declare in our own responsibility
that the product/s**Cyto-Set® Infusion,
Cyto-Set® Infusomat® Space,
Cyto-Set® Infusomat® plus**
Infusion systems for the intravenous
application of cytostatics**Cyto-Set® Pump Adapter**
Special adapter for cytostatics application
with pressure**Cyto-Set® Line,
Cyto-Set® Mix**
Connection systems for mixing and
supplying cytostatics

(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June
1993concerning Medical Devices
amended by Directive 2007/47/EC**Conformity Assessment Procedure**
according to annex II (excluding section 4)
according to annex VII and V
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class IIa
Class I sterile

Benannte Stelle

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

Datum der ersten CE-Kennzeichnung

1998-07

Gültig bis

2024-05-26

Notified Body

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

Date of first CE-marking

1998-07

Valid until

2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8250413SP	Cyto-Set® Infusomat® Space	Ila
8250414SP	Cyto-Set® Infusomat® Space	Ila
8250812SP	Cyto-Set® Infusomat® Space	Ila
8250813SP	Cyto-Set® Infusomat® Space	Ila
8250817SP	Cyto-Set® Infusomat® Space	Ila
8250819SP	Cyto-Set® Infusomat® Space	Ila
8250820SP	Cyto-Set® Infusomat® Space	Ila
8250910SP	Cyto-Set® Infusomat® Space	Ila
8250913SP	Cyto-Set® Infusomat® Space	Ila
8250916SP	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
A1672SO	Cyto-Set® Pump Adapter	Ila
A1673SO	Cyto-Set® Pump Adapter	Ila
A1685SNF	Cyto-Set® Infusion	I steril / I sterile
A1686	Cyto-Set® Infusion	I steril / I sterile
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
A25811NF	Cyto-Set® Line	Ila
A25812NF	Cyto-Set® Line	Ila
A2581NF	Cyto-Set® Line	Ila

A2582NF	Cyto-Set® Line	Ila
A2900N	Cyto-Set® Mix	Ila
A2901N	Cyto-Set® Mix	Ila
A29023N	Cyto-Set® Mix	Ila
A2902N	Cyto-Set® Mix	Ila
A2903N	Cyto-Set® Mix	Ila
A2905N	Cyto-Set® Mix	Ila
A2906N	Cyto-Set® Mix	Ila
A2907N	Cyto-Set® Mix	Ila
A2908N	Cyto-Set® Mix	Ila

Amendment Information

Version	Description of the changes
25.0	Delete Out of Market art. no. 8250814SPN
26.0	Add art. no. 8700420, 8700430, 8700440, 8700450, 8700460, 8700470, 8700480, 8700490
27.0	Delete Out of Market art. no. A2904N
28.0	Update validity
29.0	Add art. no. A2907N, A2908N

Title: Declaration of Conformity - 39.05.023 - Cyto-Set Initiator: Caroline ? Herbst

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

UserName: Herbst, Caroline (fuehcade)
Title: Administrator Regulatory Affairs
Date: Thursday, 28 May 2020, 07:04 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Seidel, Stefan (seidstde)
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems
Date: Thursday, 28 May 2020, 08:26 W. Europe Daylight Time
Meaning: Approve Document

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Friday, 29 May 2020, 08:02 W. Europe Daylight Time
Meaning: Approve Document
