

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	CytoSorbents, Inc.
Manufacturer address and contact details	305 College Road East, Princeton, NJ 08540 USA
Single Registration Number (SRN) (if available)	US-MF-000002213

Authorised Representative name (if applicable)	ICON (LR) Limited
Authorised Representative address and contact details	South County Business Park Leopardstown, Dublin 18 D18XSR3 Ireland
Single Registration Number (SRN) (if available)	IE-AR-000006507

Notified body name (if applicable)	DEKRA <input type="checkbox"/> See attached schedule
Notified body number (if applicable)	0344 <input type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	3804606CE01 <input type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	May 26, 2024 <input type="checkbox"/> See attached schedule

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

End date of extended validity/transition period

December 31, 2028 See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

Expired *before* 20 March 2023:

- Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
- A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intend to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

- Expired/expires after 20 March 2023:

Choose one applicable statement:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

Choose one applicable statement:

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: CytoSorbents Inc.

Location & Date: 305 College Road East, Princeton, NJ 08540, USA, 09/20/2023

Signature, Print Name, Title

 Matthew J. Gilliland, Senior Director, Quality/Quality Sys

Contact Details (at least email)

MatthewG@CytoSorbents.com



Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) ³ (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
CytoSorb 300 mL	3804606CE01	May 26, 2024	DEKRA - 0344	DEKRA - 0344	12/31/2028	N/A

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Wir

We

**B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germany**

erklären in eigener Verantwortung,
dass das/die Produkt/e
Kit für Dialyse und Haemo(dia)filtration
(Artikelnummern siehe Anlage I)
mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen:

Richtlinie 93/42/EWG des Rates vom
14. Juni 1993 über Medizinprodukte

Konformitätsbewertungsverfahren:
nach Anhang II mit Ausnahme der Nummer (4)
der oben genannten Richtlinie
Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie:
Klasse IIb, Regel 3
EG-Zertifikat Nr.
G1 066097 0096 Rev. 02

Konformitätsbewertungsverfahren:
nach Anhang V und Anhang VII
der oben genannten Richtlinie
Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie:
Klasse I Sterile, Regel 1
EG-Zertifikat Nr.
G2S 066097 0082 Rev. 01
Benannte Stelle:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München, Deutschland
Kennnummer 0123

Datum der ersten CE-Kennzeichnung:
2015-01

Doc #: 02/15-RA-fo
Doc Rev #: 14.0
Rev date: 2020-05-22

Gültigkeit dieser Erklärung:
von 2020-05-28
bis 2024-05-26

Radeberg, 27.05.2020


Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

hereby declare in our own responsibility
that the product/s
Kit for Dialysis and Haemo(dia)filtration
(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

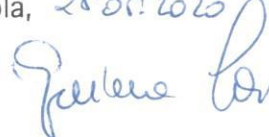
Conformity assessment procedure:
according to annex II excluding (4)
of the Directive named above
Classification
according to annex IX of the Directive named above:
Class IIb, Rule 3
EC Certificate No.
G1 066097 0096 Rev. 02

Conformity assessment procedure:
according to Annex V and Annex VII
of the Directive named above
Classification
according to annex IX of the Directive named above:
Class I Sterile, Rule 1
EC Certificate No.
G2S 066097 0082 Rev. 01
Notified body:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, Germany
Identification number 0123

Date of first CE-marking:
2015-01

Doc #: 02/15-RA-fo
Doc Rev #: 14.0
Rev date: 2020-05-22

Validity of this declaration:
from 2020-05-28
until 2024-05-26


Mirandola, 28.05.2020


Dr. Giuliana Gavioli
Head of Division RA

Anlage I / Attachment I

Art. No.	Description	Class	Rule
7211136	OMNIset Including 0.8 sqm Hemofilter	IIb	3
7211137	OMNIset Including 1.2 sqm Hemofilter	IIb	3
7211151	OMNIset Including 1.6 sqm Hemofilter	IIb	3
7211265	OMNIset Plus Including 1.6 sqm Hemofilter	IIb	3
7211427	OMNIset® Plus	IIb	3
7211432	OMNIset® ECCO ₂ R	IIb	3
7211430	OMNIset® ECCO ₂ R 1.6 m ²	IIb	3
7211287	OMNIset PRO Including 1.3 sqm Hemofilter	IIb	3
7211288	OMNIset PRO Including 1.6 sqm Hemofilter	IIb	3
7211367	OMNIset® L 1.6 m ²	IIb	3
7211368	OMNIset® 0.8 m ²	IIb	3
7211369	OMNIset® 1.2 m ²	IIb	3
7211370	OMNIset® 1.6 m ²	IIb	3
7211371	OMNIset® Pro 0.8 m ²	IIb	3
7211372	OMNIset® Pro 1.2 m ²	IIb	3
7211373	OMNIset® Pro 1.6 m ²	IIb	3
7211422	OMNIset® 1.3 m ²	IIb	3
7211423	OMNIset® 1.6 m ²	IIb	3
7211428	OMNIset® 1.3 m ²	IIb	3
7211429	OMNIset® 1.6 m ²	IIb	3
7211425	OMNIset® Pro 1.3 m ²	IIb	3
7211426	OMNIset® Pro 1.6 m ²	IIb	3
7211376	OMNIset® Pro 1.3m ²	IIb	3
7211377	OMNIset® Pro 1.6 m ²	IIb	3
7211268	OMNIset® PRO including OMNIfilter 1.3	IIb	3
7211269	OMNIset® PRO including OMNIfilter 1.6	IIb	3
7211464	OMNIset® 1.3 m ²	IIb	3
7211465	OMNIset® 1.6 m ²	IIb	3
7211065	OMNIbag 7000 mL Effluent bag	I sterile	1

Radeberg, 27.05.2020


Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

Mirandola, 25.05.2020


Dr. Giuliana Gavioli
Head of Division RA

Manufacturer's Declaration

Manufacturer name	Joline GmbH & Co. KG
Manufacturer address and contact details	Neue Rottenburger Str. 50 72379 Hechingen Germany
Single Registration Number (SRN)	DE-MF-000005494

Notified body name	DEKRA Certification GmbH
Notified body number	0124
Directive Certificate number(s) to which this confirmation is made	see attached schedule of devices
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	see attached schedule of devices
End date of extended validity/transition period	see attached schedule of devices

In relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 (MDR) as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

we, as the manufacturer, declare under our sole responsibility for the affected listed **Directive Certificates** (see attached schedule), the **listed device(s) in the attached schedule of devices** that we as their manufacturer are in compliance with the conditions listed in Article 120(3c) of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

➤ **Directive Certificate(s) as listed above or in the attached schedule**

Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards. They expire *after* 20 March 2023:

We have made formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment to our notified body no later than 26 May 2024 for the devices listed in the attached schedule. Signed written agreements with our notified body will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➤ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR is in place.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Hechingen, 2023-11-06

.....
i.A. Dr. Marian Wenzel
Director QA/RA, Person Responsible for Regulatory Compliance
Joline GmbH & Co. KG

Joline®

JOLINE GmbH & Co. KG
Neue Rottenburger Str. 50
72379 Hechingen
Germany
Phone: +49 (0) 74 71 98 81-0
Fax: +49 (0) 74 71 98 81-111

Schedule of Devices

The Manufacturer's Declaration above is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period	Substitute Device(s)
Kyphoplasty Systems ALLEVO <ul style="list-style-type: none"> • Kits • Individual Instruments 	50565-16-06	<u>2023-11-29</u>	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	<u>2028-12-31</u>	N/A
Dialysis Catheter ST <ul style="list-style-type: none"> • Kits • Catheter 	50565-16-06	<u>2023-11-29</u>	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	<u>2028-12-31</u>	N/A
Dialysis Catheter PU-LT <ul style="list-style-type: none"> • Kits • Catheter 	50565-16-06	<u>2023-11-29</u>	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	<u>2027-12-31</u>	N/A
Dialysis Catheter Silicone LT <ul style="list-style-type: none"> • Kits • Catheter 	50565-16-06	<u>2023-11-29</u>	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	<u>2027-12-31</u>	N/A
Dialysis Accessories: <ul style="list-style-type: none"> • Introducer needle 	50565-16-06	<u>2023-11-29</u>	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	<u>2028-12-31</u>	N/A
Dialysis Accessories: <ul style="list-style-type: none"> • Dilator 	50565-16-06	<u>2023-11-29</u>	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	<u>2028-12-31</u>	N/A
Dialysis Accessories: <ul style="list-style-type: none"> • Connector LT 	50565-16-06	<u>2023-11-29</u>	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	<u>2028-12-31</u>	N/A
Miniclamp	50565-17-05	<u>2023-11-29</u>	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	<u>2028-12-31</u>	N/A
Mixer	50565-17-05	<u>2023-11-29</u>	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	<u>2028-12-31</u>	N/A

Wir

We

B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germany

erklären in eigener Verantwortung,
dass das/die Produkt/e
Kit für Plasmabehandlung
(Artikelnummern siehe Anlage I)
mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen:

Richtlinie 93/42/EWG des Rates vom
14. Juni 1993 über Medizinprodukte
Konformitätsbewertungsverfahren:
nach Anhang II mit Ausnahme der nummer (4)
der oben genannten Richtlinie
Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie:
Klasse IIa, Regel 3
EG-Zertifikat Nr.
G1 066097 0096 Rev. 02


Konformitätsbewertungsverfahren:
nach Anhang V und Anhang VII
der oben genannten Richtlinie
Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie:
Klasse I Sterile, Regel 1
EG-Zertifikat Nr.
G2S 066097 0082 Rev. 01
Benannte Stelle:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München, Deutschland
Kennnummer 0123

Datum der ersten CE-Kennzeichnung:
2017-07

Doc #: 78/17-RA-fo
Doc Rev #: 7.0
Rev date: 2020-05-25

Gültigkeit dieser Erklärung:
von 2020-05-28
bis 2024-05-26

Mirandola, 2021-05-18



Francesco Benatti
Head of CoE Renal & WOC Consumables

hereby declare in our own responsibility
that the product/s
Kit for Plasma Treatment
(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
Conformity assessment procedure:
according to annex II excluding (4)
of the Directive named above
Classification
according to annex IX of the Directive named above:
Class IIa, Rule 3
EC Certificate No.
G1 066097 0096 Rev. 02

Conformity assessment procedure:
according to Annex V and Annex VII
of the Directive named above
Classification
according to annex IX of the Directive named above:
Class I Sterile, Rule 1
EC Certificate No.
G2S 066097 0082 Rev. 01
Notified body:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, Germany
Identification number 0123

Date of first CE-marking:
2017-07

Doc #: 78/17-RA-fo
Doc Rev #: 7.0
Rev date: 2020-05-25

Validity of this declaration:
from 2020-05-28
until 2024-05-26

Mirandola, 2021-05-18



Chiara Bergamini
Head of Division RA

Anlage I / Attachment I

Art. No.	Description	Class	Rule
7211153	OMNIset® TPE 0.5 m ²	Ila	3
7211154	OMNIset® TPE 0.7 m ²	Ila	3
7211467	OMNIset® TPE 0.5 m ²	Ila	3
7211468	OMNIset® TPE 0.7 m ²	Ila	3
7211065	OMNIbag 7000 mL Effluent bag	I sterile	1

Mirandola, *2021-05-18*Francesco Benatti
Head of CoE Renal & WOC ConsumablesMirandola, *2021-05-18*Chiara Bergamini
Head of Division RA

Wir

We

B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germany

erklären in eigener Verantwortung,
dass das/die Produkt/e
Kit für Plasmabehandlung
(Artikelnummern siehe Anlage I)
mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen:

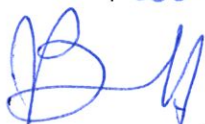
Richtlinie 93/42/EWG des Rates vom
14. Juni 1993 über Medizinprodukte
Konformitätsbewertungsverfahren:
nach Anhang II mit Ausnahme der nummer (4)
der oben genannten Richtlinie
Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie:
Klasse IIa, Regel 3
EG-Zertifikat Nr.
G1 066097 0096 Rev. 02

Konformitätsbewertungsverfahren:
nach Anhang V und Anhang VII
der oben genannten Richtlinie
Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie:
Klasse I Sterile, Regel 1
EG-Zertifikat Nr.
G2S 066097 0082 Rev. 01
Benannte Stelle:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München, Deutschland
Kennnummer 0123

Datum der ersten CE-Kennzeichnung:
2017-07

Doc #: 78/17-RA-fo
Doc Rev #: 7.0
Rev date: 2020-05-25

Gültigkeit dieser Erklärung:
von 2020-05-28
bis 2024-05-26

Mirandola, *2021-05-18*

Francesco Benatti
Head of CoE Renal & WOC Consumables

hereby declare in our own responsibility
that the product/s
Kit for Plasma Treatment
(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
Conformity assessment procedure:
according to annex II excluding (4)
of the Directive named above
Classification
according to annex IX of the Directive named above:
Class IIa, Rule 3
EC Certificate No.
G1 066097 0096 Rev. 02

Conformity assessment procedure:
according to Annex V and Annex VII
of the Directive named above
Classification
according to annex IX of the Directive named above:
Class I Sterile, Rule 1
EC Certificate No.
G2S 066097 0082 Rev. 01
Notified body:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, Germany
Identification number 0123

Date of first CE-marking:
2017-07

Doc #: 78/17-RA-fo
Doc Rev #: 7.0
Rev date: 2020-05-25

Validity of this declaration:
from 2020-05-28
until 2024-05-26

Mirandola, *2021-05-18*

Chiara Bergamini
Head of Division RA

Anlage I / Attachment I

Art. No.	Description	Class	Rule
7211153	OMNIset® TPE 0.5 m ²	Ila	3
7211154	OMNIset® TPE 0.7 m ²	Ila	3
7211467	OMNIset® TPE 0.5 m ²	Ila	3
7211468	OMNIset® TPE 0.7 m ²	Ila	3
7211065	OMNIbag 7000 mL Effluent bag	I sterile	1

Mirandola, *2024-05-18*Francesco Benatti
Head of CoE Renal & WOC ConsumablesMirandola, *2024-05-18*Chiara Bergamini
Head of Division RA

Wir

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B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germany

SRN (Single Registration No.) DE-MF-000005127

erklären in eigener Verantwortung,
dass das/die Produkt/e

Basis-UDI-DI: 40392390000016232G

Sterile Bicarbonatlösungen
(Artikelnummern siehe Anlage I)mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745
übereinstimmt/übereinstimmen**Konformitätsbewertungsverfahren**
nach Anhang IX mit Ausnahme der Nummer (II)
der oben genannten Verordnung**Klassifizierung**
gemäß Anhang VIII der oben genannten Verordnung
Klasse IIb Regel 3**EU-Zertifikat Nr.**
G10 066097 0106 Rev. 03**Benannte Stelle**
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München, Deutschland
Kennnummer 0123**Datum der ersten CE-Kennzeichnung:**
2023-03Doc #: 300/21-RA-sb
Doc Rev #: 2.0
Rev date: 2023-12-01**Gültigkeit dieser Erklärung:**
vom 2023-12-11
bis 2025-10-01hereby declare in our own responsibility
that the product/s

Basic-UDI-DI: 40392390000016232G

Sterile Bicarbonate Solution
(article numbers see attachment I)is/are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745**Conformity Assessment Procedure**
according to annex IX excluding (II)
of the Regulation named above**Classification**
according to annex VIII of the Regulation named above
Class IIb Rule 3**EU Certificate No.**
G10 066097 0106 Rev. 03**Notified Body**
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München, Germany
Identification number 0123**Date of first CE-marking:**
2023-03Doc #: 300/21-RA-sb
Doc Rev #: 2.0
Rev date: 2023-12-01**Validity of this declaration:**
from 2023-12-11
until 2025-10-01

Glandorf, 2023-12-07


Matthias Mansla
Site Manager
B. Braun Avitum AG site Glandorf

Mirandola, 2023-12-04


Chiara Bergamini
Vice President Regulatory Affairs

Anlage I / Attachment I

Art.-Nr. / Art. No.	Artikelbezeichnung / Article description	Klasse / Class	Regel / Rule
8972	Sterile Bicarbonate solution without Potassium	IIb	3
8973	Sterile Bicarbonate solution with 2 mmol/l Potassium	IIb	3
8974	Sterile Bicarbonate solution with 4 mmol/l Potassium	IIb	3

Glandorf, 2023-12-07


Matthias Mansla
Site Manager
B.Braun Avitum AG site Glandorf

Mirandola, 2023-12-06


Chiara Bergamini
Vice President Regulatory Affairs