ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
Medical Device Single Audit Program

America

C E R T I F I C A T E

No. QS6 044904 0053 Rev. 05

Certificate Holder: **B. Braun Medical Inc.**
824 Twelfth Avenue
Bethlehem PA 18018
USA

Certification Mark:

Scope of Certificate: **See Page 2 for Overall Scope Statement.**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 044904 0053 Rev. 05
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F002819**
Report No.: **721011098**
Effective Date: **2025-08-28**
Expiry Date: **2027-09-17**

Digitally signed by Ceaicovschi Tudor
Date: 2025.11.12 09:19:24 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Date of Issue: 2025-09-02

(Renee Walker)
Director, US Certification Body, MHS

MDSAP
Medical Device Single Audit Program

TÜV SÜD America

CERTIFICATE

No. QS6 044904 0053 Rev. 05

Regulatory Requirements: **Audit/Certification Criteria**

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Overall Scope Statement:

Distribution of Renal Therapy Products;

Design and Development, Production, and Distribution, including Subcontract Manufacturing Capabilities, of Non-Sterile and Sterile Medical Devices, including Infusion Systems, Pharmacy Compounding Systems, Renal Therapy Devices, Regional Anesthesia and Pain Management Devices, Vascular Access Devices, IV Sets and Accessories, Infusion Therapy Devices, Pharmaceutical Preparation and Delivery Devices, Irrigation Devices, Angioplasty Procedure Devices, and Fluid Collection Devices;

Distribution of Needles and Syringes, Wound Care Devices, Closed System Transfer Devices, Pharmaceutical Preparation and Delivery Devices, Vascular Access, IV Sets and Accessories, Fluid Collection Devices, Regional Anesthesia and Pain Management for the areas of General Hospital, Anesthesiology and Cardiovascular Usage

Facility(ies):

B. Braun Medical Inc.
824 Twelfth Avenue, Bethlehem PA 18018, USA

B. Braun US Device Manufacturing LLC
901 Marcon Boulevard, Allentown PA 18109-9341, USA

Date of Issue: 2025-09-02

(Renee Walker)
Director, US Certification Body, MHS

TÜV®

MDSAP
Medical Device Single Audit Program

TÜV SÜD America

CERTIFICATE

No. QS6 044904 0053 Rev. 05

Facility Scopes:

B. Braun Medical Inc.
824 Twelfth Avenue, Bethlehem PA 18018, USA

Corporate Headquarters and Product Registration, Distribution of Non-Sterile and Sterile Medical Devices, including Infusion Systems, Pharmacy Compounding Systems, Renal Therapy Products, Vascular Access Devices, IV Sets and Accessories, Infusion Therapy Devices, Pharmaceutical Preparation and Delivery Devices, Irrigation Devices, Angioplasty Procedure Devices, Needles and Syringes, Wound Care Devices, Closed System Transfer Devices, Fluid Collection Devices, Regional Anesthesia and Pain Management for the areas of General Hospital, Anesthesiology and Cardiovascular Usage

REPs Facility ID: F002819

B. Braun US Device Manufacturing LLC
901 Marcon Boulevard, Allentown PA 18109-9341, USA

Design and Development, Production, and Distribution, including Subcontract Manufacturing Capabilities, of Non-Sterile and Sterile Medical Devices, including Infusion Systems, Pharmacy Compounding Systems, Renal Therapy Devices, Regional Anesthesia and Pain Management Devices, Vascular Access Devices, IV Sets and Accessories, Infusion Therapy Devices, Pharmaceutical Preparation and Delivery Devices, Irrigation Devices, Angioplasty Procedure Devices, and Fluid Collection Devices for the areas of General Hospital, Anesthesiology and Cardiovascular Usage

REPs Facility ID: F002819

Date of Issue: 2025-09-02

(Renee Walker)
Director, US Certification Body, MHS

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 044904 0046 Rev. 04

Holder of Certificate: **B. Braun Medical Inc.**
824 Twelfth Avenue
Bethlehem PA 18018
USA

Certification Mark:

Scope of Certificate: **Design and Development, Production, and Distribution of Non-active Devices for Anesthesia, Emergency, Intensive Care, Injection, and Infusion; Provision of Manufacturing Services for General Non-active, Non-implantable Medical Devices**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 044904 0046 Rev. 04

Report No.: 721011098

Valid from: 2025-08-29
Valid until: 2027-09-04

Date, 2025-08-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 044904 0046 Rev. 04

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

B. Braun US Device Manufacturing LLC
901 Marcon Boulevard, Allentown PA 18109-9341, USA

Design and Development, Manufacturing, Subcontracting, Packaging, and Sterilization of Non-active Devices for Anesthesia, Emergency, Intensive Care, Injection, and Infusion

B. Braun Medical Inc.
824 Twelfth Avenue, Bethlehem PA 18018, USA

Design and Development, Production, and Distribution of Non-active Devices for Anesthesia, Emergency, Intensive Care, injection, and Infusion; Provision of Manufacturing Services for General Non-active, Non-Implantable Medical Devices

-

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 066097 0106 Rev. 03

Manufacturer:

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

SRN Manufacturer - DE-MF-000005127

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 066097 0106 Rev. 03

Report No.: 713258363_G10change

Preceding Certificate No.: G10 066097 0106 Rev. 02

Valid from: 2023-11-23
Valid until: 2025-10-01

Date of Initial Issuance: 2021-06-16

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-11-23

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 066097 0106 Rev. 03

Classification:	Class IIb
Device Group:	Z120902 - HAEMODIALYSIS INSTRUMENTS
Intended Purpose:	Equipment for extracorporeal blood treatments to administer and remove substances and body fluids

Classification:	Class IIb
Device Group:	D99 - DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES - OTHER
Intended Purpose:	Liquid concentrates for the cleaning, decalcification and heat-disinfection of the fluid pathways of hemodialysis machines

Classification:	Class IIb
Device Group:	Z120990 - VARIOUS NEPHROLOGY AND HAEMODIALYSIS INSTRUMENTS
Intended Purpose:	Production of water for diluting hemodialysis concentrates

Classification:	Class IIb
Device Group:	F0499 - DIALYSIS CONCENTRATES - OTHER
Intended Purpose:	Ready-to-use solution for extracorporeal blood treatment

Classification:	Class IIb
Device Group:	F0306 - CONTINUOUS DIALYSIS KITS
Intended Purpose:	Sets consisting of extracorporeal circuits and filters for continuous blood purification treatment

Classification:	Class IIb
Device Group:	F040201 - DIALYSIS CONCENTRATES, BASIC SOLUTIONS, POWDER
Intended Purpose:	Alkaline concentrates to be used in bicarbonate hemodialysis or hemodiafiltration

Classification:	Class IIb
Device Group:	F010601 - DIALYSERS - UFC < 18 ml/h/mmHg
Intended Purpose:	Dialyzers to be used in hemodialysis and hemo(dia)filtration

Classification:	Class IIb
Device Group:	F010602 - DIALYSERS - UFC = 18 - 35 ml/h/mmHg
Intended Purpose:	Dialyzers to be used in hemodialysis and hemo(dia)filtration

Classification:	Class IIb
Device Group:	F010603 - DIALYSERS - UFC > 35 ml/h/mmHg

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD
Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 066097 0106 Rev. 03

Intended Purpose:	Dialyzers to be used in hemodialysis and hemo(dia)filtration
Classification:	Class IIb
Device Group:	F040101 - DIALYSIS CONCENTRATES, ACID SOLUTIONS, NON-STERILE
Intended Purpose:	Acidic concentrate for bicarbonate hemodialysis or hemodiafiltration
Classification:	Class IIb
Device Group:	F040202 - DIALYSIS CONCENTRATES, BASIC SOLUTIONS, LIQUID
Intended Purpose:	Alkaline concentrates to be used in bicarbonate hemodialysis or hemodiafiltration
Classification:	Class IIb
Device Group:	B030201 - PLASMAPHERESIS DEVICES AND KITS
Intended Purpose:	Apheresis set
Classification:	Class IIa
Device Group:	F020102 - ARTERIOVENOUS DIALYSIS LINES, TWO NEEDLES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	F020104 - REINFUSION DIALYSIS LINES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	F020199 - ARTERIOVENOUS DIALYSIS LINES FOR HAEMODIALYSIS - HAEMOFILTRATION - HAEMODIAFILTRATION - OTHER
Intended Purpose:	-
Classification:	Class IIa
Device Group:	B030201 - PLASMAPHERESIS DEVICES AND KITS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	F900301 - HAEMODIALYSIS ADAPTORS
Intended Purpose:	-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 066097 0106 Rev. 03

Classification: Class IIa
Device Group: A010401 - ARTERIOVENOUS FISTULA NEEDLES
Intended Purpose: -

Classification: Class IIa
Device Group: C010280 - CENTRAL VENOUS CATHETERS - ACCESSORIES
Intended Purpose: -

Classification: Class IIa
Device Group: F0305 - HAEMOPERFUSION KITS
Intended Purpose: -

Classification: Class IIa
Device Group: F0301 - HAEMOFILTRATION-HAEMODIAFILTRATION KITS
Intended Purpose: -

Classification: Class IIa
Device Group: F0303 - HAEMODIALYSIS KITS
Intended Purpose: -

Classification: Class IIa
Device Group: B0380 - APHERESIS DEVICES - ACCESSORIES
Intended Purpose: -

Classification: Class IIa
Device Group: F0306 - CONTINUOUS DIALYSIS KITS
Intended Purpose: -

Classification: Class IIa
Device Group: F0307 - ULTRAFILTRATION KITS
Intended Purpose: -

Classification: Class IIa
Device Group: F020180 - ARTERIOVENOUS DIALYSIS LINES FOR HAEMODIALYSIS - HAEMOFILTRATION - HAEMODIAFILTRATION - ACCESSORIES
Intended Purpose: -

Classification: Class IIa

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 066097 0106 Rev. 03

Device Group: A010499 - DIALYSIS NEEDLES - OTHER
Intended Purpose: -

Classification: Class IIa
Device Group: B030299 - APHERESIS THERAPY DEVICES - OTHER
Intended Purpose: -

Classification: Class IIa
Device Group: B0399 - APHERESIS DEVICES - OTHER
Intended Purpose: -

Classification: Class IIa
Device Group: F020101 - ARTERIOVENOUS DIALYSIS LINES, ONE NEEDLE
Intended Purpose: -

Classification: Class IIa
Device Group: F0199 - HAEMODIALYSIS FILTERS - OTHER
Intended Purpose: -

Classification: Class IIa
Device Group: Z120990 - VARIOUS NEPHROLOGY AND HAEMODIALYSIS INSTRUMENTS
Intended Purpose: -

The validity of this certificate depends on conditions and/or is limited to the following: .None.

Revision History:

Rev.	Dated	Report	Description
00	2021-06-16	713175105	-
01	2022-03-03	713175105	-
02	2023-02-20	713221085_DIV_G10change	-
03	2023-11-23	713258363_G10change	Supplemented: Device(s)/group of device(s) added

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Wir

We

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

hereby declare in our own responsibility
that the product/s

Basis-UDI-DI: 403923900000016232G

Basic-UDI-DI: 403923900000016232G

Sterile Bicarbonatlösungen
(Artikelnummern siehe Anlage I)

Sterile Bicarbonate Solution
(article numbers see attachment I)

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745
übereinstimmt/übereinstimmen

is/are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745

Konformitätsbewertungsverfahren
nach Anhang IX mit ausnahme der nummer (II)
der oben genannten Verordnung

Conformity Assessment Procedure
according to annex IX excluding (II)
of the Regulation named above

Klassifizierung
gemäß Anhang VIII der oben genannten Verordnung
Klasse IIb Regel 3

Classification
according to annex VIII of the Regulation named above
Class IIb Rule 3

EU-Zertifikat Nr.
G10 066097 0106 Rev. 03

EU Certificate No.
G10 066097 0106 Rev. 03

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

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

Datum der ersten CE-Kennzeichnung:
2023-03

Date of first CE-marking:
2023-03

Doc #: 300/21-RA-sb
Doc Rev #: 2.0
Rev date: 2023-12-01

Doc #: 300/21-RA-sb
Doc Rev #: 2.0
Rev date: 2023-12-01

Gültigkeit dieser Erklärung:
vom 2023-12-11
bis 2025-10-01

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, 2023-12-04

Chiara Bergamini
Vice President Regulatory Affairs

DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

Joline GmbH & Co. KG
Mr. Dr. Marian Wenzel
Neue Rottenburger Str. 50
72379 Hechingen
Germany

DEKRA Certification GmbH
Handwerkstraße 15
D-70565 Stuttgart

Contact Stephanie Donner
Phone -
Fax +49.711.7861-2615
Email stephanie.donner@dekra.com

Headquarters
Phone +49.711.7861-2566
Fax +49.711.7861-2615

Date 2023-11-29

Subject: Notified Body Confirmation Letter

Our reference: 50565-CoL-01, Rev.0

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Dr. Wenzel,

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Joline GmbH & Co. KG
Neue Rottenburger Str. 50
72379 Hechingen
Deutschland

SRN Number: DE-MF-000005494

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables 1 and 2 below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive MDD. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive MDD.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the

date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments) >

On behalf of the Notified Body,

Stephanie Donner
2023-11-29

Digitally signed by Stephanie Donner
Date: 2023-11-29 15:41:00+01:00

Enclosures:

Confirmation Letter Annex

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Product or product group identification acc. to MDD - certificate	MDD Device classification	MDD Certificate and Certificate Annex No. with revision	MDR Application ID
MD 0106 **Kyphoplasty Systems ALLEVO** - **Kits** - **Individual Instruments**	Class IIa	Certificate 50565-16-06 Annex Rev. 2	A22051293
MD 0102 **Dialysis Catheter ST** - **Kits** - **Catheter**	Class IIa	Certificate 50565-16-06 Annex Rev. 2	A22071097
MD 0203 **Dialysis Catheter PU-LT** - **Kits** - **Catheter**	Class III	Certificate 50565-16-06 Annex Rev. 2	A22071097
MD 0203 **Dialysis Catheter Silicone LT** - **Kits** - **Catheter**	Class III	Certificate 50565-16-06 Annex Rev. 2	A22071097
MD0101 **Miniclamp**	Class Is	Certificate 50565-17-05 Annex Rev. 0	A22051293
MD 0106 **Mixer**	Class Is	Certificate 50565-17-05 Annex Rev. 0	A21091017

Joline®

JOLINE GmbH & Co. KG • Neue Rottenburger Str. 50 • D-72379 Hechingen

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:

JOLINE GmbH & Co. KG • Neue Rottenburger Str. 50 • D-72379 Hechingen

➢ **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:

JOLINE GmbH & Co. KG
Neue Rottenburger Str. 50
72379 Hechingen
Germany
Phone: +49 (0) 7471 9881-0
Fax: +49 (0) 7471 9881-111

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 • D-72379 Hechingen

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 • Kits • Individual Instruments	50565-16-06	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2028-12-31**	N/A
Dialysis Catheter ST • Kits • Catheter	50565-16-06	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2028-12-31**	N/A
Dialysis Catheter PU-LT • Kits • Catheter	50565-16-06	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2027-12-31**	N/A
Dialysis Catheter Silicone LT • Kits • Catheter	50565-16-06	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2027-12-31**	N/A
Dialysis Accessories: • Introducer needle	50565-16-06	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2028-12-31**	N/A
Dialysis Accessories: • Dilator	50565-16-06	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2028-12-31**	N/A
Dialysis Accessories: • Connector LT	50565-16-06	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2028-12-31**	N/A
Miniclamp	50565-17-05	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2028-12-31**	N/A
Mixer	50565-17-05	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2028-12-31**	N/A

CytoSorbents

Seven Deer Park Drive, Suite K
Monmouth Junction, NJ 08852
P 732.329.8885
F 732.329.8650
www.cytosorbents.com

Declaration of Conformity
Polymer Based Adsorption Systems

CytoSorbents Inc. has the sole responsibility that the distributed CE marked products, specified in the annexed product list, conform to the applicable regulatory requirements covered by:

CE Marking of Conformity Certificate Certificate #3804606CE01	
Description	**Date**
Initial Certification	March 25, 2011
Renewal	September 01, 2013
Renewal	September 01, 2016
Renewal	July 22, 2019

Delivered by DEKRA Certification B.V., Notified Body Identification Number 0344, in accordance with Annex II of the EC-Directive, the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIb according to Annex IX, Rule 3[1] , meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive. The conformity of the full quality assurance system set out in Annex II, is described in the said CE Marking of Conformity Certificate, issued and delivered by DEKRA Certification B.V.

[1] Rule 3 – All non-invasive devices intended for modifying the biological or chemical composition of blood, other body fluids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.

CytoSorbents

Seven Deer Park Drive, Suite K
Monmouth Junction, NJ 08852
P 732.329.8885
F 732.329.8650
www.cytosorbents.com

This Declaration of Conform covers Polymer Based Adsorption Systems as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following sites:

CytoSorbents Inc.
7 Deer Park Drive
Suite K
Monmouth Junction, NJ 08852
United States of America

CytoSorbents Inc.
11 Deer Park Drive
Suite 125
Monmouth Junction, NJ 08852
United States of America

Retaining the EC Authorized Representative:

MedPass SAS
95 bis Boulevard Pereire
75017 Paris
France

Matthew J. Gilliland
Director, Quality/Quality Systems

CytoSorbents Incorporated
7 Deer Park Drive
Suite K
Monmouth Junction
New Jersey 08852
www.CytoSorbents.com

19 AUG 2019
Date

Annex: Product List

- CytoSorb 300mL Device

CytoSorbents

Seven Deer Park Drive, Suite K
Monmouth Junction, NJ 08852
Tel 732.329.8885
Fax 732.329.8650

Declarație de conformitate
Sisteme de adsorbție pe bază de polimeri

CytoSorbents Inc. are responsabilitatea exclusivă asupra conformității produselor marcate CE distribuite, specificate în lista de produse anexată, cu cerințele normative aplicabile, acoperite de:

Certificat de Conformitate CE **Certificat nr. 3804606CE01**	
Descriere	**Data**
Prima certificare	25 martie 2011
Reînnoire	1 septembrie 2013
Reînnoire	1 septembrie 2016
Reînnoire	22 iulie 2019

Emis de DEKRA Certification BV, Organism notificat cu nr. de identificare 0344, conform cu Anexa II la Directiva CE, Directiva Consiliului 93/42/CEE din 14 iunie 1993 privind dispozitivele medicale.

În plus, asigurăm și declarăm că produsele marcate CE distribuite, așa cum sunt menționate și încadrate în Clasa IIb conform cu Anexa IX, norma 3[1], întrunesc prevederile Directivei CE care li se aplică.

Prezenta declarație se bazează pe aplicarea sistemului de calitate aprobat pentru proiectarea, producția și inspecția finală a produselor vizate, în concordanță cu Anexa II la Directiva CE. Conformitatea sistemului complet de asigurare a calității stabilit în Anexa II este descrisă în Certificatul de conformitate CE emis și comunicat de DEKRA Certification BV.

[1] Norma 3 – toate dispozitivele neinvazive concepute pentru modificarea compoziției biologice sau chimice a sângelui, altor fluide corporale sau altor lichide destinate infuzării în organism sunt încadrate în Clasa IIb, dacă tratamentul nu constă din filtrarea, centrifugarea sau schimbul de gaze, căldură, caz în care sunt încadrate în Clasa IIa.

CytoSorbents

Seven Deer Park Drive, Suite K
Monmouth Junction, NJ 08852
Tel 732.329.8885
Fax 732.329.8650

Prezenta declarație de conformitate acoperă sistemele de adsorbție pe bază de polimeri specificate în lista de produse atașată la această declarație și este valabilă pentru toate produsele vizate care poartă marcajul CE și sunt fabricate în următoarele unități:

CytoSorbents Inc.
7 Deer Park Drive
Suite K
Monmouth Junction, NJ 08852
Statele Unite ale Americii

CytoSorbents Inc.
7 Deer Park Drive
Suite K
Monmouth Junction, NJ 08852
Statele Unite ale Americii

Reprezentant autorizat în CE:

MedPass SAS
95 bis Boulevard Pereire
75017 Paris
Franța

[semnătură indescifrabilă] [ștampila rotundă CytoSorbents Inc.] 19 august 2019
Matthew J. Gilliland Data
Director, Calitate/Sisteme de Calitate

Anexă: Lista de produse

- Dispozitiv CytoSorb 300 ml