Digitally signed by Roibu Tatiana
Date: 2024.07.02 10:08:49 EEST
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TEHNOMEDICA"
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de indentificare de stat - codul fiscal
1002600053256

Data înregistrării **17.04.2002**

Data eliberării **16.02.2005**

Bolboceanu Adela, registrator de stat
Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT 109 L.Ș.

MD 0027040

F/COM/CC/23/02

Nr. CIF26-842.2020
Data: 13 Februarie 2020

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **Mobiasbanca - OTP Group S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **TEHNOMEDICA S.R.L.** cod fiscal (IDNO) **1002600053256**, detine următoarele conturi curente la Mobiasbanca - OTP Group S.A., Sucursala. 26 Negruzzi:

1. **MDL - MD65MO2224ASV98310887100**
2. **EUR - MD06MO2224ASV98311097100**

L.Ş.

Numele, Prenumele si Semnătura
Director sucursalei „Gheorghe Mocanu"

Executor :Eduard Cilcic
Tel: 022-812-150

Mobiasbanca - OTP Group S.A. • Capital Social: 100 000 000 MDL • Număr de înregistrare de stat – 1002600006089
bd. Ştefan cel Mare şi Sfînt 81A • MD-2012 Chişinău, Moldova • telefon: +373 22 256 456 • e-mail: info@mobiasbanca.md • www.mobiasbanca.md

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. **1968** din **01.02.2019**

Denumirea completă: **SOCIETATEA CU RĂSPUNDERE LIMITATĂ «TEHNOMEDICA» .**
Denumirea prescurtată: **«TEHNOMEDICA» S.R.L. .**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat şi codul fiscal: **1002600053256.**
Data înregistrării de stat: **17.04.2002.**
Sediul: **MD-2001, str. Ciuflea, 38/1, mun.Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1 Fabricarea utilajului medical şi chirurgical şi a dispozitivelor ortopedice;
2 Comerţul cu ridicata al produselor farmaceutice;
3 Comerţul cu amănuntul al produselor farmaceutice;
4 Practica medicală;
5 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;
6 Activităţi de consultare pentru afaceri şi management.
Capitalul social: **5400** lei.
Administrator: ROIBU TATIANA,
Asociaţi:
1. ROIBU TATIANA 100 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 01.02.2019.

Specialist coordonator
tel. 022-20-7838

Clichici Elena

INSTITUŢIA PUBLICĂ AGENŢIA SERVICII PUBLICE IDNO 1002600024700 REPUBLICA MOLDOVA CHIŞINĂU 003

EB 0257484

Date cu caracter personal. **Operator: I.P. "Agenţia Servicii Publice" IO 0000059**

GUVERNUL REPUBLICII MOLDOVA

SERVICIUL FISCAL DE STAT

MCabinet
PORTALUL GUVERNAMENTAL AL CETĂȚEANULUI ȘI AL UNITĂȚILOR DE DREPT

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr. № **1613256**

Din От **01.07.2024 16:13**

DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare
Фискальный код / Идентификационный номер

1002600053256

Denumirea
Наименование

SOCIETATEA CU RĂSPUNDERE LIMITATĂ TEHNOMEDICA

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСВИЯ ИЛИ НАЛИЧИЯ ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie
На дату выдачи данной справки задолжность перед национальном публичным бюджетом составляет

0 MDL

VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО **16.07.2024 16:13**

Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответсвие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предостоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la **01.07.2024 16:13**

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022
Сертификат подписан электронной попдписью в соответсвие с Законом № 124 от 19.05.2022

Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are aceiași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц (mcabinet.gov.md) и подписан электронной подписью владельца портала и имеет такаю же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлиности электронной подписи можно осуществить с помощью Государсвенной Службой Электронной Подписью (msign.gov.md)

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Anexa nr. 8
la Documentația standard nr.115
din 15.09.2021

DECLARAŢIE
privind valabilitatea ofertei

Către **IMSP Institutul de Medicină Urgentă**

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, privind achiziționarea Consumabilelor pentru dispozitivul de monitorizare arterială (REPETAT) prin procedura de achiziție COP nr.ocds-b3wdp1-MD-1719301722213/21242867 din 04.07.2024, pentru o durată de 60 zile (șaizeci zile) din data deschiderii ofertei, și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 02.07.2024

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către IMSP Institutul de Medicină Urgentă

În atenția Grupului de lucru
al procedurii nr.ocds-b3wdp1-MD-1719301722213/21242867

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 3 zile de la solicitarea autorității contractante pentru produsele oferite în cadrul procedurii prenonate.

Cu respect,

Director Tatiana Roibu

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către IMSP Institutul de Medicină Urgentă

În atenția Grupului de lucru
al procedurii nr.ocds-b3wdp1-MD-1719301722213/21242867

DECLARAŢIE

privind înregistrarea în Registrul de Stat al Dispozitivelor Medicale al Agenției Medicamentului și Dispozitivelor Medicale

Prin prezenta, declarăm că produsele oferite în cadrul procedurii prenotate sunt înregistrate în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale.

Dovada înregistrării dispozitivelor medicale se regăsește pe pagina web a Agenției Medicamentului și Dispozitivelor Medicale www.amdm.gov.md.

DM000401802	CATETER PENTRU MĂSURAREA PRESIUNII ARTERIALE	ARTERIOFIX 20 G/160 MM	5206332	Germania	B. BRAUN MELSUNGEN AG	TEHNOMEDICA S.R.L.	Rg04-000003	01.04.2023
DM000401803	CATETER PENTRU MĂSURAREA PRESIUNII ARTERIALE	ARTERIOFIX 18 G/160 MM	5206359	Germania	B. BRAUN MELSUNGEN AG	TEHNOMEDICA S.R.L.	Rg04-000003	04.01.2023

Cu respect,

Director Tatiana Roibu

B BRAUN

Konformitätserklärung
Declaration of Conformity

Document-No.:	39.05.641
Revision-No.:	15
Effective Date:	2020-05-19
Page:	1 of 2

Wir | We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany

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

Arteriofix

Arterienpunktionskanülen, Arterien-Katheter-Set
(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG

Konformitätsbewertungsverfahren
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa / Regel 7

Benannte Stelle
TÜV SÜD Product Service GmbH (ID-Nr. 0123)
Ridlerstraße 65, 80339 München, Deutschland

Ausgestellte Bescheinigung(en):
G1 012974 0608 Rev. 00

Datum der ersten CE-Kennzeichnung
1996-06-13

Gültig bis
2024-05-26

hereby declare in our own responsibility
that the product/s

Arteriofix

Arterial puncture needle, Arterial Catheter Set
(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC

Conformity Assessment Procedure
according to annex II (excluding section 4)
of the Council Directive named above

Classification
according to annex IX of the
Council Directive named above
Class IIa / Rule 7

Notified Body
TÜV SÜD Product Service GmbH (ID-No. 0123)
Ridlerstraße 65, 80339 Munich, Germany

Certificate(s) issued:
G1 012974 0608 Rev. 00

Date of first CE-marking
1996-06-13

Valid until
2024-05-26

Berlin, 2020-05-19

B. Braun Melsungen AG

i. A.

Dr. S. Vogelbein
Head of Quality Management CoE VS

Berlin, 2020-05-19

B. Braun Melsungen AG

i. V.

Dr. H. Schlicht
Head of Regulatory Affairs

Anlage I / Attachment I

Art.-Nr. / Art. No.	Artikelbezeichnung	Article description	Klasse / Class
5206316	Arteriofix Art.-Kath.-Set 22G/80 mm	Arteriofix 22G/80 mm	IIa
5206324	Arteriofix Art.-Kath.-Set 20G/80 mm	Arteriofix 20G/80 mm	IIa
5206332	Arteriofix Art.-Kath.-Set 20G/160 mm	Arteriofix 20G/160 mm	IIa
5206359	Arteriofix Art.-Kath.-Set 18G/160 mm	Arteriofix 18G/160 mm	IIa
5206345	Arteriofix Art.-Kath.-Set 18G/80 mm	Arteriofix 18G/80 mm	IIa

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	B.Braun Melsungen AG
Manufacturer address and contact details	Carl-Braun-Str. 1, 34212 Melsungen, Germany Contact Person: Dr. Henning Schlicht, Head of Regulatory Affairs, Email: henning.schlicht@bbraun.com
Single Registration Number (SRN) (if available)	DE-MF-000000201

Authorised Representative name (if applicable)	n/a
Authorised Representative address and contact details	n/a
Single Registration Number (SRN) (if available)	n/a

[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.

Effective

Notified body name (if applicable)	TÜV SÜD Product Service GmbH	☐ See attached schedule
Notified body number (if applicable)	CE0123	☐ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	G1 012974 0608 Rev. 00	☐ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26	☐ See attached schedule
End date of extended validity/transition period	2028-12-31	☐ 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

[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

Effective

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 intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒ 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:

	Quality Management	**Regulatory Affairs**
Full Company Name	**B.Braun Melsungen AG**	**B.Braun Melsungen AG**
Location & Date	**Berlin, 2024-05-22**	**Berlin, 2024-05-22**
Signature	**See electronic signature**	**See electronic signature**
Print Name	**Dr. Susanne Vogelbein**	**Dr. Henning Schlicht**
Title	**Head of QM**	**Head of RA**
Contact Details (at least email)	**susanne.vogelbein@bbraun.com**	**henning.schlicht@bbraun.com**
Version of document	**V03**	

Effective

Effective

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)
Angiodyn High Pressure Tubes						
5011507	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5011515	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5011523	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5011531	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5011938	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5011957	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5011965	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5011973	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5014824	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5014875	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5016002	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5018200	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	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)

Effective

5018218	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5018233	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5018580	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5018864	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5218088	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
Unique Kissing BiBalloon Adapter						
5014760	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
Combitrans/Angiotrans						
5200011	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5200181	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5214040
5200182	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5215454
5200183	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5215050
5200756	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5200830
5200757	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5202507
5200758	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5202620
5200759	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5202604
5200830	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5200849	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5201152	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5202507	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5202604	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5202614	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5202617	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5202620	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a

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5203660	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5206994	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5207167	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5211247	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5212391	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5213505	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5215454
5213516	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5215050
5213527	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5214040
5216200	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5201152-1	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5201152
5202507-0	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5202507
5202604-1	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5202604
5202620-1	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5202620
5311010	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5202620
5311325	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5215050
5312020	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5202604
5313030	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5202604
5318575	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5206994
5318762	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5201152
5318766	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5200849
5318767	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5201152
5318768	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5200849
5318771	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5201152
5318776	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5207167
5319289	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5202620
5319290	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5202604

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5319295	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5215454
5319300	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5215050
5319305	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5201152
5319771	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5200849
5019505	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5200359	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5200411
5213940	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5200411
Inflation Device						
5028901	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
Arteriofix						
5206316	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5206324	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5206332	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5206359	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5206345	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
Arteriofix V						
5206364	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5206363	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5206362	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5206361	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
Angiodyn Syringes						
5010120	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5010142
5010142	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a

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5011990	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5010142
5014866	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5018998
5017469	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5018998
5018991	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5018992	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5018993	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5018996	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5018997	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5018998	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5019004	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5019006	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5019013	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5019016	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
Angiodyn Manifolds and Stopcocks						
5010575	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5010576	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5010577	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5010579	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5016131	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5011406	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5011407	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5011404	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5012074	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5012112	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5012759	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a

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5012813	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5012155	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5012163
5012163	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5015569	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5019506	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5200411	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5212871	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5018161	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5018170	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
Angiodyn Contrast Saver						
5010551	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5010557
5010552	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5010557	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5010559	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5014001	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5019715
Angiodyn Guidewires						
5050472	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5050529	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5053535	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
Y-Connectors						
5010434	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5019602	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5022693
5021596	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a

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5021693	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5020743	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5022693	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5024103	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5022693
5017826	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5022693
Intradyn Tear-Away						
5010848	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5010849	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5010851	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5210313
5210313	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5210593	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5210321	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5210330	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5210348	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5214297	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5210585
5210585	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5014882	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5014883	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5014884	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5211869	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5210313
5211870	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5010848
5212537	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5210348
5214698	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5210330
5214699	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5210593

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Intradyn Venous						
5209749	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5209757	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5209765	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5210615	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5210062	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5209749
5210070	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5209757
5210089	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5209765
5210950	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5210100	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5210097	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5210178	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5150020	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5150021	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
Combidyn Pressure Tubes						
5201272	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5201281	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5201337	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5201345	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5204950	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5204995	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5205239	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5210577	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5214993	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a

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5215019	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5215027	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5215035	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5215043	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5215264	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5218598	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5204941	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5204976	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5204984	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5204992	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5205000	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5205018	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5205026	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5205034	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5205042	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5205050	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5205255	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5205263	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5205271	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5208000	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5208020	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5208080	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5208090	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5208599	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5211280	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a

Effective

Puncture Needles						
5013606	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5013862	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
5208505	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	n/a
PTCA Kits						
5028550	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5021693
5028902	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5028901
5028904	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5014760
5028905	G1 012974 0608 Rev. 00	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2028-12-31	5028901

Change History

Version	Date	Description of Change
01	2024-04-25	Initial Version
02	2024-05-07	NB Number on p2 corrected to CE0123
03	2024-05-22	Certificate Revision No. added

Effective

Title: B. Braun Melsungen AG_VS_manufacturer confirmation letter_Regulation EU 2023-607_G10_V03.pdf Initiator: Henning ? Schlicht

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

UserName: Schlicht, Henning (schlhgde)
Title: Head of Regulatory Affairs
Date: Thursday, 23 May 2024, 09:12 W. Europe Daylight Time
Meaning: Document signed as Author
==========

UserName: Vogelbein, Susanne (vogesude)
Title: Head of Quality Management
Date: Tuesday, 28 May 2024, 08:13 W. Europe Daylight Time
Meaning: Approve Document
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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 012974 0608 Rev. 00

Manufacturer: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies): **Coronary stent systems, PTCA catheters, PTA catheters, PTCA sets, Probes for stimulation and Electrophysiology, Angiography sets, manifolds, guide wires, tubes and syringes, single use Right heart pulmonary artery catheters, Monitoring sets for invasive physiological pressure measurement, Introducer sheaths and sets, Arterial puncture cannulae, arterial catheter sets**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713168177

Valid from: 2020-05-06
Valid until: 2024-05-26

Date, 2020-05-14

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
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No. G1 012974 0608 Rev. 00

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

TÜV SÜD Product Service

Certificate

No. Q5 012974 0606 Rev. 01

Holder of Certificate: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Certification Mark:

Scope of Certificate: **Design and development, production and distribution of sterile single use products for angiography, surgery, angioplasty, stimulation, coronary stent systems, PTCA catheters, PTA catheters, PTCA sets, probes for stimulation and electrophysiology, procedure kits, angiography sets, manifolds, guide wires, tubes, syringes, single use right heart pulmonary artery catheters, monitoring sets for invasive physiological pressure measurement, introducer sheaths and sets, arterial puncture cannula, arterial catheter sets**

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 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:Q5 012974 0606 Rev. 01

Report No.: 713263785

Valid from: 2022-10-07
Valid until: 2025-09-30

Date, 2022-10-07

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service

Certificate

No. Q5 012974 0606 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

B. Braun Melsungen AG Vascular Systems
Sieversufer 8, 12359 Berlin, GERMANY

Design and development, production and distribution of sterile single use products for angiography, surgery, angioplasty, stimulation, coronary stent systems, PTCA catheters, PTA catheters, PTCA sets, probes for stimulation and electrophysiology, procedure kits, angiography sets, manifolds, guide wires, tubes, syringes, single use right heart pulmonary artery catheters, monitoring sets for invasive physiological pressure measurement, introducer sheaths and sets, arterial puncture cannula, arterial catheter sets

B. Braun Melsungen AG Vascular Systems
Mistelweg 2, 12357 Berlin, GERMANY

Production (extrusion) of non-sterile tubing for catheter production

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