

Manufacturer's Declaration Regarding Regulation 2023/607

with respect to the 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 their validity per Article 120.2 of Regulation (EU) 2017/745 on Medical Devices as amended by Regulation (EU) 2023/607 of 20 March 2023 (MDR) and with respect to the devices' – including 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 – and their manufacturer's compliance with the conditions to continued placing on the market or putting into service per Article 120.3c of the MDR:

Manufacturer Name	Cordis Cashel
Manufacturer Address	Cahir Road, Cashel Co Tipperary, Ireland
Single Registration Number (SRN), (if available)	IE-MF-000018690

Authorised Representative Name (if applicable)	Not Applicable
Authorised Representative Address	
Single Registration Number (SRN) (if available)	

Notified Body Name (if applicable)	See attached schedule
Notified Body Number (if applicable)	See attached schedule
Directive Certificate Number to which this confirmation is made (if applicable)	See attached schedule
Date of validity as indicated on the Directive Certificate(s) (if applicable)	See attached schedule
End date of extended validity/ transition period	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
- 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) – if applicable** - 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covering the listed device(s) was/were issued after 25 May 2017, was/were valid 26 May 2021, was/were not withdrawn by 20 March 2023, and
 - *Choose applicable statement:*
 - ☐ did expire before 20 March 2023
 - ☐ before its date of expiry, a formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII, MDR for conformity assessment was made for the devices(s) listed in the attached schedule or its substitute and a signed written agreement was in place in accordance with Section 4.3, second subparagraph, of Annex VII.
 - ☐ a Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR,
 - ☐ a Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure.
 - ☒ did not expire before 20 March 2023
 - ☒ Where certificates expire *after* 20 March 2023, a formal application to the notified body in accordance with Section 4.3, first subparagraph, of Annex VII MDR for conformity assessment has been made or will be made/submitted to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is or will be in place in accordance with Section 4.3, second subparagraph, of Annex VII MDR before 26 September 2024.
 - ☐ Where certificates expire after 20 March 2023 and before 26 May 2024, if the manufacturer does not lodge an application for conformity assessment by 26 May 2024, the transition period will end on 26 May 2024.
- **Quality Management System (QMS)**
 - Choose applicable statement:*
 - ☐ A QMS in accordance with Article 10(9) MDR has been put in place.
 - ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.
 - ☒ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024

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

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- 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.

- We acknowledge that requirements relating to **post-market surveillance, vigilance, registration of economic operators** and of devices in accordance with MDR apply for the device families as listed in the attached schedule.

Signed for and on behalf of the Manufacturer:

Company Name: Cordis Cashel

Location: Cahir Road, Cashel, Co. Tipperary, Ireland

Printed Name: Nicola Parry

Title: EMEA Quality Systems Lead

Signature:

Date: 28-Jun-2023

DOLPH McGRATH,
1, Old Waterford Road,
Clonmel,
CO. TIPPERARY, IRELAND
Notary Public for the
County of Tipperary.
Commissioned for Life



SCHEDULE OF DEVICES

Identification of the device (e.g., device name, family/group name device model or catalogue number)		Number of the Directive Certificate(s)	Validity Date as indicated on the Directive Certificate(s)	Notified Body	Extended Validity Date or Transition Period
				Name and Number	
One-Piece Angiographic Needles with snap-on wing	502652	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
One-Piece Angiographic Needles with snap-on wing	502654	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
One-Piece Angiographic Needles with snap-on wing	502655	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Two-Piece Angiographic Needle with snap-on wing	502657	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Two-Piece Angiographic Needle with snap-on wing	502658	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
One-Piece Angiographic Needles with snap-on wing	502659	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002002S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002002X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002003S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002003X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002004S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002004X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002006S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002006X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002008S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002008X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002010S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002010X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002015S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002015X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002020S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002020X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002025S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28

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Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002025X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002030S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002030X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002502S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002502X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002503S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002503X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002504S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002504X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002506S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002506X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002508S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002508X	CE 556903	21 Sep 23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002510S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002510X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002515S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002515X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002520S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002520X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002525S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002525X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28

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Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002530S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48002530X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003002S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003002X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003003S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003003X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003004S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003004X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003006S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003006X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003008S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003008X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003010S	CE 556903	21 Sep 23	BSI/2797	21 Dec 28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003010X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003015S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003015X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003020S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003020X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003025S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003025X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003030S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28

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Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003030X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003502X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003503S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003503X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003504S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003504X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003506X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003508S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003508X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003510S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003510X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003515S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003515X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003520S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003520X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003525S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003525X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003530S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003530X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004002S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004002X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28

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				Name and Number	
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004003S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004003X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004004S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004004X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004006S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004006X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004008S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004008X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004010S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004010X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004015S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004015X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004020S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004020X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004025S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004025X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004030S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48004030X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005002S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005002X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005003X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28

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				Name and Number	
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005004S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005004X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005006S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005006X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005008S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005008X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005010S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005010X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005015S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005015X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005020S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005020X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005025S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005025X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005030S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005030X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006002S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006002X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006004S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006004X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006006S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28

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				Name and Number	
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006006X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006008S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006008X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006010S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006010X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006015S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006015X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006020S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006020X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006025S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006025X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006030S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006030X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48007002S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48007002X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48007003S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48007003X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48007004S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48007004X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48007006S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48007006X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28

Identification of the device (e.g., device name, family/group name device model or catalogue number)		Number of the Directive Certificate(s)	Validity Date as indicated on the Directive Certificate(s)	Notified Body	Extended Validity Date or Transition Period
				Name and Number	
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48007008X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48007010S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48007010X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48008002S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48008002X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48008004S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48008004X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48008006S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48008006X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48008008X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48008010S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48008010X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48009002S	CE 556903	21 Sep 23	BSI/2797	21 Dec 28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48009004S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48009006S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48010002S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48010003S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48010004S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48010008S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48010010S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003502S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28

Identification of the device (e.g., device name, family/group name device model or catalogue number)		Number of the Directive Certificate(s)	Validity Date as indicated on the Directive Certificate(s)	Notified Body	Extended Validity Date or Transition Period
				Name and Number	
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48003506S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48005003S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006003S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48006003X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48007008S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48008003S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48008003X	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48008008S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48009003S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48009008S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48009010S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Saber™ Percutaneous Transluminal Angioplasty Dilatation Catheter	48010006S	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002002L	CE 556903	21-Sep-23	BSI/2797	21 Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002003L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002004L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002006L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002008L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002010L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002015L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002020L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002025L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28

Identification of the device (e.g., device name, family/group name device model or catalogue number)		Number of the Directive Certificate(s)	Validity Date as indicated on the Directive Certificate(s)	Notified Body	Extended Validity Date or Transition Period
				Name and Number	
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002030L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002502L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002503L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002504L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002506L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002508L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002510L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002515L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002520L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002525L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51002530L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003002L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003003L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003004L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003006L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003008L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003010L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003015L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003020L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003025L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003030L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28

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SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003502L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003503L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003504L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003506L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003508L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003510L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003515L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003520L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003525L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51003530L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51004002L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51004003L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51004004L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51004006L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51004008L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51004010L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51004015L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51004020L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51004025L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51004030L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51005002L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28

Identification of the device (e.g., device name, family/group name device model or catalogue number)		Number of the Directive Certificate(s)	Validity Date as indicated on the Directive Certificate(s)	Notified Body	Extended Validity Date or Transition Period
				Name and Number	
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51005003L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51005004L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51005006L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51005008L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51005010L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51005015L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51005020L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51005025L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51005030L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51006002L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51006003L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51006004L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51006006L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51006008L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51006010L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51006015L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51006020L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51006025L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51006030L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51007002L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51007003L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28

Identification of the device (e.g., device name, family/group name device model or catalogue number)		Number of the Directive Certificate(s)	Validity Date as indicated on the Directive Certificate(s)	Notified Body Name and Number	Extended Validity Date or Transition Period
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51007004L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51007006L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51007008L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51007010L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51008002L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51008003L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51008004L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51008006L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51008008L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
SaberX™ Radianz Percutaneous Transluminal Angioplasty Dilatation Catheter	R51008010L	CE 556903	21-Sep-23	BSI/2797	21-Dec-28
Palmaz Blue .014 Peripheral Stent System	PB1240PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1240PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1250PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1260PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1260PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1270PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1270PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1540PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1540PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1550PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1550PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1560PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1560PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1570PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1570PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1840PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1840PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1850PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1850PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1860PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1860PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1870PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027

Identification of the device (e.g., device name, family/group name device model or catalogue number)		Number of the Directive Certificate(s)	Validity Date as indicated on the Directive Certificate(s)	Notified Body	Extended Validity Date or Transition Period
				Name and Number	
Palmaz Blue .014 Peripheral Stent System	PB1870PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB2440PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB2450PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB2460PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB2460PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB2470PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB1250PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB2450PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .014 Peripheral Stent System	PB2470PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1240PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1250PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1250PSX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1260PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1260PSX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1270PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1540PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1550PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1550PSX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1560PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1560PSX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1570PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1840PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1850PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1850PSX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1860PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1860PSX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1870PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB1870PSX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB2440PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB2450PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB2450PSX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB2460PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB2460PSX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB2470PSS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Blue .018 Peripheral Stent System	PB2470PSX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1250PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1270PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1270PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027

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				Name and Number	
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1280PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1280PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1540PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1550PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1560PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1570PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1580PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1580PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1840PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1850PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1850PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1860PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1860PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1870PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1870PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1880PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1880PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1910PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1910PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1990PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1990PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027

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Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2440PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2450PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2460PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2460PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2470PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2470PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2480PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2480PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2510PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2590PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2590PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2910PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2910PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2960PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2960PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2970PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2970PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2980PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2980PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2990PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2990PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027

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Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG3910PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG3910PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG3950PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG3950PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG3960PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG3960PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG3970PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG3970PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG3980PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG3980PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG3990PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG3990PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG5910PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG5910PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG5950PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG5950PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG5960PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG5960PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG5970PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG5970PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG5980PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027

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				Name and Number	
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG5980PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG5990PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG5990PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG7910PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG7960PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG7960PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG7970PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG7970PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG7980PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG7980PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG7990PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG7990PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1250PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1260PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1260PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1550PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1560PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG1570PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2510PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2950PPS	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Palmaz Genesis Peripheral Stent on Opta® Pro .035 Delivery System	PG2950PPX	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05030MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027

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				Name and Number	
SmartFlex Stent Vascular System (SFA)	SF05030SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05040MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05040SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05060MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05060SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05080MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05080SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05100MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05100SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05120MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05120SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05150MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05150SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05200MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF05200SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06030MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06030SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06040MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06040SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06060MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06060SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06080MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06080SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06100MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06100SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06120MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06120SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06150MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06150SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06200MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF06200SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07030MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07030SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07040MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07040SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07060MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07060SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07080MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07080SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07100MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07100SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027

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				Name and Number	
SmartFlex Stent Vascular System (SFA)	SF07120MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07120SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07150MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07150SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07200MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF07200SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08030MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08030SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08040MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08040SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08060MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08060SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08080MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08080SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08100MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08100SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08120MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08120SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08150MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08200MV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08200SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
SmartFlex Stent Vascular System (SFA)	SF08150SV	CE 556903	21-Sep-23	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	AB2298	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	AB2698	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	AB3098	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	AB3498	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	AE2204	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	AE2604	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	AE3004	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	AE3404	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL1008	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL1010	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL1012	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL1014	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL1308	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL1310	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL1312	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL1314	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL1608	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL1610	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL1612	CE 633652	5/26/2024	BSI/2797	12/31/2027

Identification of the device (e.g., device name, family/group name device model or catalogue number)		Number of the Directive Certificate(s)	Validity Date as indicated on the Directive Certificate(s)	Notified Body	Extended Validity Date or Transition Period
				Name and Number	
Incraft AAA Stent Graft System	IL1614	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL2008	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL2010	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL2012	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL2014	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL2410	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL2412	CE 633652	5/26/2024	BSI/2797	12/31/2027
Incraft AAA Stent Graft System	IL2414	CE 633652	5/26/2024	BSI/2797	12/31/2027
OptEase Retrievable Vena Cava Filter	466F210AF	CE 560271	05/07/2023	BSI/2797	12/31/2027
OptEase Retrievable Vena Cava Filter	466F210AJ	CE 560271	05/07/2023	BSI/2797	12/31/2027
OptEase Retrievable Vena Cava Filter	466F210BJ	CE 560271	05/07/2023	BSI/2797	12/31/2027