Manufacturer's Declaration

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

- the validity of certificates issued Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- 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	JOTEC GmbH
Manufacturer address and contact details	Lotzenäcker 23 72379 Hechingen, Germany info.europe@artivion.com
Single Registration Number (SRN) (if available)	DE-MF-000005709

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

Notified body name (if applicable)	DEKRA Certification GmbH ☒ See attached schedule
Notified body number (if applicable)	0124 ☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	EC 50736-16-08 Rev. 0 ☒ 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	2027-12-31 ☒ 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*
- 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covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.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: **N/A**
  ☐ Expired *before* 20 March 2023:
  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:
  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  ☐ We do not 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**

  N/A

  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 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:

JOTEC GmbH

Hechingen, 27-Sep-2024

Signiert von Florian Tyrs
Ich genehmige dieses Dokument
27-Sep-2024 | 6:32:44 AM EDT
C17C32E633654ADB8FABBDB6FB7A3B73

Florian Tyrs
Vice President Global Operations and General Manager
Florian.tyrs@artivion.com

Signed by Dr. Cornelia Kuschel
I approve this document
27-Sep-2024 | 3:28:21 AM EDT
26BB58D77EAE49098F48AAF6BAC9766D

Dr. Cornelia Kuschel
Director Regulatory Affairs

Cornelia.kuschel@artivion.com

Schedule of Devices

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

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period
E-wire Guide Wire	EC 50736-16-08 Rev. 0	2024-05-26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124 Application lodged Contract signed	31.12.2027
E-xpand Stent Graft Balloon Catheter	EC 50736-16-08 Rev. 0	2024-05-26		DEKRA Certification GmbH 0124 Application lodged Contract signed	31.12.2027
FlowLine Bipore ePTFE Vascular Graft	EC 50736-16-08 Rev. 0	2024-05-26		DEKRA Certification GmbH 0124 Application lodged Contract signed	31.12.2027
E-liac Stent Graft System	EC 50736-16-08 Rev. 0	2024-05-26		DEKRA Certification GmbH 0124 Application lodged Contract signed	31.12.2027
Textile Vascular Grafts: FlowWeave BIOSEAL, FlowNit BIOSEAL	EC 50736-16-08 Rev. 0 DEC 50736-53-A6 Rev. 0	2024-05-26		DEKRA Certification GmbH 0124 Application lodged Contract signed	31.12.2027
E-tegra Stent Graft System	EC 50736-16-08 Rev. 0 DEC 50736-23-J1 Rev. 2	2024-05-26		DEKRA Certification GmbH 0124 Application lodged Contract signed	31.12.2027
E-nside TAAA Multibranch Stent Graft System	EC 50736-16-08 Rev. 0 DEC 50736-23-K0 Rev. 0	2024-05-26		DEKRA Certification GmbH 0124 Application lodged Contract signed	31.12.2027
E-vita OPEN NEO	EC 50736-16-08 Rev. 0 DEC 50736-23-M1 Rev. 0	2024-05-26		DEKRA Certification GmbH 0124 Application lodged Contract signed	31.12.2027

Attached a list of catalogue numbers for each device.

Product List

FlowLine Bipore ePTFE Vascular Graft

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
Thin Wall		
10TW1005N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW2006N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW2007N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW2008N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW4005N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW5006N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW5007N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW5008N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW7005N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW8006N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW8007N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW8008N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
Thin Wall with Spiral Reinforcement		
10TW1005S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW4005S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW5006S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW5007S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW5008S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW7005S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW8006S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW8007S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10TW8008S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
Standard Wall		
10SW2006N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10SW2007N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10SW4005N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10SW5006N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10SW5007N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10SW5008N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10SW7005N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10SW8006N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10SW8007N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
10SW8008N	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
Standard Wall with Spiral Reinforcement		
10SW5006S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10SW5007S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10SW5008S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10SW8006S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10SW8007S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08
10SW8008S	FlowLine Bipore ePTFE Vascular Graft	50736-16-08

FlowNit Bioseal Textile Vascular Graft

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
Bifurcations		
35BI1206	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35BI1407	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35BI1608	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35BI1809	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35BI2010	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35BI2211	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35BI2412	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
Straight Tubes		
35ST1506	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST1507	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST1508	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST1510	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST1512	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST1514	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST1516	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST1518	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST1520	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST1522	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST1524	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST3006	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST3007	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST3008	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST3010	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST3012	FlowNit Bioseal Textile Vascular Graft	50736-53-A6

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
35ST3014	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST3016	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST3018	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST3020	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST3022	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST3024	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST4506	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST4507	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST6006	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST6007	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST6008	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST6010	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST6012	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST6014	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST0008	FlowNit Bioseal Textile Vascular Graft	50736-53-A6
35ST0010	FlowNit Bioseal Textile Vascular Graft	50736-53-A6

FlowWeave Bioseal Textile Vascular Graft

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
Straight Tubes		
45ST1508	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1510	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1512	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1514	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1516	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1518	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1520	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1522	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1524	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1526	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1528	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1530	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1532	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1534	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1536	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST1538	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3006	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
45ST3008	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3010	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3012	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3014	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3016	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3018	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3020	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3022	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3024	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3026	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3028	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3030	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3032	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3034	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3036	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST3038	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6006	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6008	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6010	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6012	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6014	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6016	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6018	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6020	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6022	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6024	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6026	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6028	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6030	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6032	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6034	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6036	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6
45ST6038	FlowWeave Bioseal Textile Vascular Graft	50736-53-A6

E-nside TAAA Multibranch Stent Graft System

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
65MU383021-4B8866-00	E-nside TAAA Multibranch Stent Graft System	50736-23-K0

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
65MU382621-4B8866-00	E-nside TAAA Multibranch Stent Graft System	50736-23-K0
65MU333021-4B8866-00	E-nside TAAA Multibranch Stent Graft System	50736-23-K0
65MU332621-4B8866-00	E-nside TAAA Multibranch Stent Graft System	50736-23-K0

E-vita OPEN NEO

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
Straight Graft Configuration		
95HG2620L120-C01	E-vita OPEN NEO	50736-23-M1
95HG2620L175-C01	E-vita OPEN NEO	50736-23-M1
95HG2622L120-C01	E-vita OPEN NEO	50736-23-M1
95HG2622L175-C01	E-vita OPEN NEO	50736-23-M1
95HG2624L120-C01	E-vita OPEN NEO	50736-23-M1
95HG2624L175-C01	E-vita OPEN NEO	50736-23-M1
95HG2626L120-C01	E-vita OPEN NEO	50736-23-M1
95HG2626L180-C01	E-vita OPEN NEO	50736-23-M1
95HG2828L120-C01	E-vita OPEN NEO	50736-23-M1
95HG2828L180-C01	E-vita OPEN NEO	50736-23-M1
95HG3030L120-C01	E-vita OPEN NEO	50736-23-M1
95HG3030L180-C01	E-vita OPEN NEO	50736-23-M1
95HG3033L130-C01	E-vita OPEN NEO	50736-23-M1
95HG3033L180-C01	E-vita OPEN NEO	50736-23-M1
95HG3036L130-C01	E-vita OPEN NEO	50736-23-M1
95HG3036L180-C01	E-vita OPEN NEO	50736-23-M1
95HG3040L130-C01	E-vita OPEN NEO	50736-23-M1
95HG3040L180-C01	E-vita OPEN NEO	50736-23-M1
Branched Graft Configuration		
95HG2620L120-C02	E-vita OPEN NEO	50736-23-M1
95HG2620L175-C02	E-vita OPEN NEO	50736-23-M1
95HG2622L120-C02	E-vita OPEN NEO	50736-23-M1
95HG2622L175-C02	E-vita OPEN NEO	50736-23-M1
95HG2624L120-C02	E-vita OPEN NEO	50736-23-M1
95HG2624L175-C02	E-vita OPEN NEO	50736-23-M1
95HG2626L120-C02	E-vita OPEN NEO	50736-23-M1
95HG2626L180-C02	E-vita OPEN NEO	50736-23-M1
95HG2828L120-C02	E-vita OPEN NEO	50736-23-M1
95HG2828L180-C02	E-vita OPEN NEO	50736-23-M1

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
95HG3030L120-C02	E-vita OPEN NEO	50736-23-M1
95HG3030L180-C02	E-vita OPEN NEO	50736-23-M1
95HG3033L130-C02	E-vita OPEN NEO	50736-23-M1
95HG3033L180-C02	E-vita OPEN NEO	50736-23-M1
95HG3036L130-C02	E-vita OPEN NEO	50736-23-M1
95HG3036L180-C02	E-vita OPEN NEO	50736-23-M1
95HG3040L130-C02	E-vita OPEN NEO	50736-23-M1
95HG3040L180-C02	E-vita OPEN NEO	50736-23-M1
Trifurcated Graft Configuration		
95HG2620L175-C03	E-vita OPEN NEO	50736-23-M1
95HG2622L175-C03	E-vita OPEN NEO	50736-23-M1
95HG2624L175-C03	E-vita OPEN NEO	50736-23-M1
95HG2626L180-C03	E-vita OPEN NEO	50736-23-M1
95HG2828L180-C03	E-vita OPEN NEO	50736-23-M1
95HG3030L180-C03	E-vita OPEN NEO	50736-23-M1
95HG3033L180-C03	E-vita OPEN NEO	50736-23-M1
95HG3036L180-C03	E-vita OPEN NEO	50736-23-M1
95HG3040L180-C03	E-vita OPEN NEO	50736-23-M1

E-tegra Stent Graft System

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
Main Body		
93MB2310L15-08	E-tegra Stent Graft System	50736-23-J1
93MB2313L10-08	E-tegra Stent Graft System	50736-23-J1
93MB2313L13-08	E-tegra Stent Graft System	50736-23-J1
93MB2313L13-10	E-tegra Stent Graft System	50736-23-J1
93MB2313L15-08	E-tegra Stent Graft System	50736-23-J1
93MB2316L15-08	E-tegra Stent Graft System	50736-23-J1
93MB2322L17-10	E-tegra Stent Graft System	50736-23-J1
93MB2610L15-08	E-tegra Stent Graft System	50736-23-J1
93MB2613L10-08	E-tegra Stent Graft System	50736-23-J1
93MB2613L13-08	E-tegra Stent Graft System	50736-23-J1
93MB2613L13-10	E-tegra Stent Graft System	50736-23-J1
93MB2613L15-08	E-tegra Stent Graft System	50736-23-J1
93MB2616L15-08	E-tegra Stent Graft System	50736-23-J1
93MB2622L17-10	E-tegra Stent Graft System	50736-23-J1

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
93MB2910L15-08	E-tegra Stent Graft System	50736-23-J1
93MB2913L10-08	E-tegra Stent Graft System	50736-23-J1
93MB2913L13-08	E-tegra Stent Graft System	50736-23-J1
93MB2913L13-10	E-tegra Stent Graft System	50736-23-J1
93MB2913L15-08	E-tegra Stent Graft System	50736-23-J1
93MB2916L15-08	E-tegra Stent Graft System	50736-23-J1
93MB2919L15-10	E-tegra Stent Graft System	50736-23-J1
93MB2922L17-10	E-tegra Stent Graft System	50736-23-J1
93MB3210L15-08	E-tegra Stent Graft System	50736-23-J1
93MB3213L10-08	E-tegra Stent Graft System	50736-23-J1
93MB3213L13-10	E-tegra Stent Graft System	50736-23-J1
93MB3216L15-08	E-tegra Stent Graft System	50736-23-J1
93MB3219L15-10	E-tegra Stent Graft System	50736-23-J1
93MB3222L17-10	E-tegra Stent Graft System	50736-23-J1
93MB3610L15-08	E-tegra Stent Graft System	50736-23-J1
93MB3613L10-08	E-tegra Stent Graft System	50736-23-J1
93MB3613L13-10	E-tegra Stent Graft System	50736-23-J1
93MB3616L15-08	E-tegra Stent Graft System	50736-23-J1
93MB3619L15-10	E-tegra Stent Graft System	50736-23-J1
93MB3622L17-10	E-tegra Stent Graft System	50736-23-J1
Contralateral Leg		
93CL1510L05	E-tegra Stent Graft System	50736-23-J1
93CL1510L07	E-tegra Stent Graft System	50736-23-J1
93CL1510L09	E-tegra Stent Graft System	50736-23-J1
93CL1510L10	E-tegra Stent Graft System	50736-23-J1
93CL1513L05	E-tegra Stent Graft System	50736-23-J1
93CL1513L07	E-tegra Stent Graft System	50736-23-J1
93CL1513L09	E-tegra Stent Graft System	50736-23-J1
93CL1513L10	E-tegra Stent Graft System	50736-23-J1
93CL1516L03	E-tegra Stent Graft System	50736-23-J1
93CL1516L05	E-tegra Stent Graft System	50736-23-J1
93CL1516L07	E-tegra Stent Graft System	50736-23-J1
93CL1516L09	E-tegra Stent Graft System	50736-23-J1
93CL1516L10	E-tegra Stent Graft System	50736-23-J1
93CL1519L05	E-tegra Stent Graft System	50736-23-J1
93CL1519L07	E-tegra Stent Graft System	50736-23-J1
93CL1519L09	E-tegra Stent Graft System	50736-23-J1
93CL1519L10	E-tegra Stent Graft System	50736-23-J1

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
93CL1522L05	E-tegra Stent Graft System	50736-23-J1
93CL1522L07	E-tegra Stent Graft System	50736-23-J1
93CL1522L09	E-tegra Stent Graft System	50736-23-J1
93CL1522L10	E-tegra Stent Graft System	50736-23-J1
93CL1525L05	E-tegra Stent Graft System	50736-23-J1
93CL1525L07	E-tegra Stent Graft System	50736-23-J1
93CL1525L09	E-tegra Stent Graft System	50736-23-J1
93CL1525L10	E-tegra Stent Graft System	50736-23-J1
Iliac Extension		
93IE1310L05	E-tegra Stent Graft System	50736-23-J1
93IE1313L05	E-tegra Stent Graft System	50736-23-J1
93IE1913L05	E-tegra Stent Graft System	50736-23-J1
93IE1919L05	E-tegra Stent Graft System	50736-23-J1
93IE1922L05	E-tegra Stent Graft System	50736-23-J1
93IE2219L05	E-tegra Stent Graft System	50736-23-J1
93IE2222L05	E-tegra Stent Graft System	50736-23-J1
93IE2227L05	E-tegra Stent Graft System	50736-23-J1
93IE2722L05	E-tegra Stent Graft System	50736-23-J1
93IE2727L05	E-tegra Stent Graft System	50736-23-J1
Aortic Extension		
93AE2323L05	E-tegra Stent Graft System	50736-23-J1
93AE2626L05	E-tegra Stent Graft System	50736-23-J1
93AE2929L05	E-tegra Stent Graft System	50736-23-J1
93AE3232L05	E-tegra Stent Graft System	50736-23-J1
93AE3636L05	E-tegra Stent Graft System	50736-23-J1
93AE3838L05	E-tegra Stent Graft System	50736-23-J1
Aorto Uni Iliac Stent Graft		
93AU2313L11	E-tegra Stent Graft System	50736-23-J1
93AU2613L11	E-tegra Stent Graft System	50736-23-J1
93AU2913L11	E-tegra Stent Graft System	50736-23-J1
93AU3213L11	E-tegra Stent Graft System	50736-23-J1
93AU3613L11	E-tegra Stent Graft System	50736-23-J1

E-liac Stent Graft System

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
Isolated Iliac Aneurysms		

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
72IB1410L65L44	E-liac Stent Graft System	50736-16-08
72IB1412L65L44	E-liac Stent Graft System	50736-16-08
72IB1414L65L44	E-liac Stent Graft System	50736-16-08
72IB1412L65L56	E-liac Stent Graft System	50736-16-08
72IB1414L65L56	E-liac Stent Graft System	50736-16-08
72IB1610L65L56	E-liac Stent Graft System	50736-16-08
72IB1612L65L56	E-liac Stent Graft System	50736-16-08
72IB1614L65L56	E-liac Stent Graft System	50736-16-08
72IB1812L65L56	E-liac Stent Graft System	50736-16-08
72IB1814L65L56	E-liac Stent Graft System	50736-16-08
Aorto-iliac Aneurysms		
72IB1410L53L44	E-liac Stent Graft System	50736-16-08
72IB1412L53L44	E-liac Stent Graft System	50736-16-08
72IB1414L53L44	E-liac Stent Graft System	50736-16-08
72IB1410L53L56	E-liac Stent Graft System	50736-16-08
72IB1412L53L56	E-liac Stent Graft System	50736-16-08
72IB1414L53L56	E-liac Stent Graft System	50736-16-08

E-wire Guide Wire

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
76XX3035N-06	E-wire Guide Wire	50736-16-08
76XX1935N-06	E-wire Guide Wire	50736-16-08

E-xpand Stent Graft Balloon Catheter

Catalogue No.	Device Name	No. of Certificate by Notified Body DEKRA
85XX0050N35-00	E-xpand Stent Graft Balloon Catheter	50736-16-08

DocuSign

Certificate Of Completion

Envelope Id: 12C0A19241954F3BA44C9DDD28C46B46
Status: Completed
Subject: Complete with Docusign: 2024-09-27_mdr_manufacturer-declaration_JOTEC.pdf
Source Envelope:
Document Pages: 13
Signatures: 2
Certificate Pages: 2
Initials: 0
AutoNav: Enabled
EnvelopeId Stamping: Enabled
Time Zone: (UTC-05:00) Eastern Time (US & Canada)

Envelope Originator:
Corinna Höfling
1655 Roberts Blvd. NW
Kennesaw, GA 30144
Corinna.Hoefling@artivion.com
IP Address: 46.5.254.139

Record Tracking

Status: Original
9/27/2024 1:49:09 AM
Holder: Corinna Höfling
Corinna.Hoefling@artivion.com
Location: DocuSign

Signer Events	Signature	Timestamp
Dr. Cornelia Kuschel Cornelia.Kuschel@artivion.com Director Regulatory Affairs Security Level: Email, Account Authentication (Required)	 Signature Adoption: Drawn on Device Signature ID: 26BB58D7-7EAE-4909-8F48-AAF6BAC9766D Using IP Address: 87.191.49.82 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 9/27/2024 1:51:32 AM Viewed: 9/27/2024 3:28:13 AM Signed: 9/27/2024 3:28:29 AM
Electronic Record and Signature Disclosure: Not Offered via DocuSign		
Florian Tyrs Florian.Tyrs@artivion.com General Manager Hechingen, Director Operations Hechingen Artivion Inc., JOTEC GmbH Security Level: Email, Account Authentication (Required)	 Signature Adoption: Uploaded Signature Image Signature ID: C17C32E6-3365-4ADB-8FAB-BDB6FB7A3B73 Using IP Address: 87.191.49.82 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): Ich genehmige dieses Dokument	Sent: 9/27/2024 1:51:32 AM Viewed: 9/27/2024 6:32:34 AM Signed: 9/27/2024 6:32:52 AM
Electronic Record and Signature Disclosure: Not Offered via DocuSign		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	9/27/2024 1:51:32 AM
Certified Delivered	Security Checked	9/27/2024 6:32:34 AM
Signing Complete	Security Checked	9/27/2024 6:32:52 AM
Completed	Security Checked	9/27/2024 6:32:52 AM

Payment Events	Status	Timestamps