CERTIFICATE

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the company

JOTEC GmbH

Scope of certification:

Development, manufacturing and distribution of medical devices for the treatment of vascular diseases. Manufacturing of Matricart and ePTFE tubes

Certified location:

Lotzenäcker 23, 72379 Hechingen, Germany

(further locations see annex)

Digitally signed by Captari Alexandru
Date: 2021.03.22 10:57:15 EET
Reason: MoldSign Signature
Location: Moldova

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50736-Z5Ü1-00.

This certificate is valid from 2019-03-27 to 2021-03-26

Registration No.: 50736-14-00

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15 DEKRA DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-03-27

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

84460

Annex to the Certificate No. 50736-14-00

Revision status: 0

valid from 2019-03-27 to 2021-03-26

The following locations belong to the certificate above:

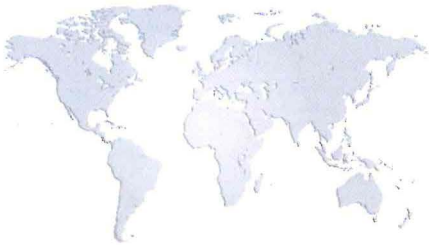
	Headquarters	Certified location	Scope of certification
	JOTEC GmbH	Lotzenäcker 23 D-72379 Hechingen	Development, manufacturing and distribution of medical devices for the treatment of vascular diseases. Manufacturing of Matricart and ePTFE tubes.
	Subsidiaries	**Certified locations**	**Scope of certification**
1.	JOTEC GmbH	Lotzenäcker 25 D-72379 Hechingen	Manufacturing of the stent springs. Storage of medical products for the treatment of vascular diseases. Laboratories for development and microbiology.
2.	JOTEC GmbH	Etzental 64-4 D-72379 Hechingen	Preparation and testing of the yarns used in the knitting and weaving of vascular prostheses. Raw material warehouse.

DEKRA Certification GmbH • DEKRA Certification • D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-03-27

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

JOTEC GmbH

Lotzenäcker 23, 72379 Hechingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50736-Z5Ü1-00, the decision dated 2019-03-27 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-03-27 to 2024-03-26

Registration No.: 50736-16-06

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-03-27
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-BS-295.10.02

84460

Annex to the EC Certificate No. 50736-16-06

Revision status: 0

Valid from 2019-03-27 to 2024-03-26

Devices/device categories included in the certificate:

Class II a:

- E-wire Guide Wire
- E-xpand Stent Graft Balloon Catheter

Class II b:

- FlowLine Bipore ePTFE Vascular graft
- E-liac Stent Graft System
- E-ventus BX Peripheral Stent Graft System

Class III:

- Textile vascular grafts: FlowWeave, FlowNit, FlowWeave Bioseal, FlowNit Bioseal
- FlowLine Bipore Heparin ePTFE Vascular graft
- FlowWeave plus Textile Vascular graft
- E-XL Aortic Stent
- E-vita thoracic 3G Stent Graft System
- E-vita open plus Stent Graft System
- E-vita abdominal XT Stent Graft System
- E-tegra Stent Graft System

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565 DEKRA DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-03-27
Notified Body ID-number: 0124

84460

JOTEC® | FlowLine BIPORE®

Peripheral Treatment with ePTFE

CryoLife®
Life Restoring Technologies®

FlowLine BIPORE

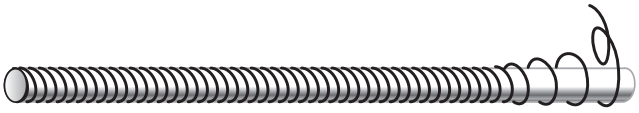
- Specific BIPORE configuration with two different fibril lengths to ensure low thrombogenicity
- Additional ePTFE wrapping for enhanced suture retention and high burst strength*
- Unique guideline indicates diameter and wall thickness of the graft
- Helical reinforcement for increased resistance against kinking and compression
- Excellent and pliable handling and suture behaviour
- Simple and easy removal of the spiral reinforcement

Ordering Information

Thin Wall	Thin wall reinforced		
Catalog No.	Catalog No.	Ø (mm)	Length (cm)
10TW2006N	-	6	20
10TW5006N	10TW5006S	6	50
10TW8006N	10TW8006S	6	80
10TW2007N	-	7	20
10TW5007N	10TW5007S	7	50
10TW8007N	10TW8007S	7	80
10TW2008N	-	8	20
10TW5008N	10TW5008S	8	50
10TW8008N	10TW8008S	8	80

Standard wall	Standard wall reinforced		
Catalog No.	Catalog No.	Ø (mm)	Length (cm)
10SW2006N	-	6	20
10SW5006N	10SW5006S	6	50
10SW8006N	10SW8006S	6	80
10SW2007N	-	7	20
10SW5007N	10SW5007S	7	50
10SW8007N	10SW8007S	7	80
10SW5008N	10SW5008S	8	50
10SW8008N	10SW8008S	8	80

FlowLine BIPORE



FlowLine BIPORE Reinforced

* Bench test data on file at JOTEC GmbH. Data not indicative of clinical performance.

JT-BR-0100200-EN V02 08/2019

JOTEC GmbH, a fully owned subsidiary of CryoLife, Inc.

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CryoLife® Life Restoring Technologies®