

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)

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


Ruth Delbeck-Bayer



DEKRA Certification GmbH Stuttgart; 2019-03-27



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	Etzentel 64-4 D-72379 Hechingen	Preparation and testing of the yarns used in the knitting and weaving of vascular prostheses. Raw material warehouse.


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

Ruth Delbeck-Bayer



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

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



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

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:

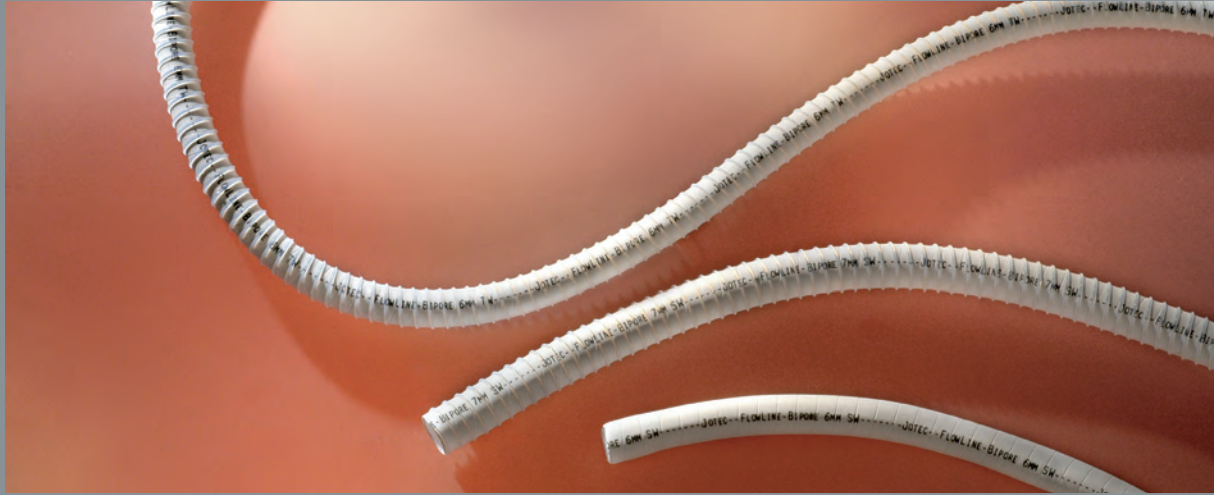
- Textile vascular grafts: FlowWeave, FlowNit, FlowWeave Bioseal, FlowNit Bioseal
- FlowLine Bipore Heparin ePTFE Vascular graft
- FlowWeave plus Textile Vascular graft
- E-XL Aortic Stent
- E-vita thoracic 3G Stent Graft System
- E-vita open plus Stent Graft System
- E-vita abdominal XT Stent Graft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



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

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FlowLine Bipore®

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- Unique Bipore® design with two different fibril lengths for low thrombogenicity
- An additional ePTFE wrap guarantees enhanced suture retention and high burst strength
- Unique guideline indicates diameter and wall thickness of the graft
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ePTFE Vascular Grafts

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Thin Wall

Thin Wall with spiral reinforcement

Length (cm)	Diameter (mm)	Catalogue No.	Catalogue No.
10	5	10TW1005N	10TW1005S
20	6	10TW2006N	–
20	7	10TW2007N	–
20	8	10TW2008N	–
40	5	10TW4005N	10TW4005S
40	6	10TW4006N	–
50	6	10TW5006N	10TW5006S
50	7	10TW5007N	10TW5007S
50	8	10TW5008N	10TW5008S
70	5	10TW7005N	10TW7005S
80	6	10TW8006N	10TW8006S
80	7	10TW8007N	10TW8007S
80	8	10TW8008N	10TW8008S

Standard Wall

Standard Wall with spiral reinforcement

Length (cm)	Diameter (mm)	Catalogue No.	Catalogue No.
20	6	10SW2006N	–
20	7	10SW2007N	–
40	5	10SW4005N	–
50	6	10SW5006N	10SW5006S
50	7	10SW5007N	10SW5007S
50	8	10SW5008N	10SW5008S
70	5	10SW7005N	10SW7005S
80	6	10SW8006N	10SW8006S
80	7	10SW8007N	10SW8007S
80	8	10SW8008N	10SW8008S

JOTEC®

SOLUTIONS FOR VASCULAR DISEASE

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