

CERTIFICATE



EN ISO 13485:2012 + AC:2012

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 disease. 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-Z5-00.

This certificate is valid from 2018-03-27 to 2019-03-31

Registration No.: 50736-11-03

Ruth Delbeck-Bayer



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-03-12



Deutsche
Akkreditierungsstelle
D-ZM-16029-08-00



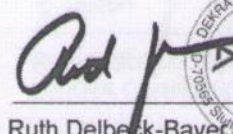
Annex to the Certificate No. 50736-11-03

Revision status: 0

valid from 2018-03-27 to 2019-03-31

The following locations belong to the certificate above:

	Headquarters	Certified location	Scope of certification
1.	JOTEC GmbH	Lotzenäcker 23 D-72379 Hechingen	Development, manufacturing and distribution of medical devices for the treatment of vascular disease. Manufacturing of Matricart and ePTFE tubes
	Subsidiaries	Certified locations	Scope of certification
2.	JOTEC GmbH	Lotzenäcker 25 D-72379 Hechingen	Manufacturing of stent springs. Storage of medical devices for the treatment of vascular diseases
3.	JOTEC GmbH	Lotzenäcker 17 D-72379 Hechingen	Preparation and testing of the yarns used in the knitting and weaving of vascular prostheses
4.	JOTEC GmbH	Lotzenäcker 9 D-72379 Hechingen	Laboratories for development and microbiological testing


Ruth Delbeck-Bayer

DEKRA Certification GmbH, Stuttgart, 2018-03-12

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



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-Z5-00, the decision dated 2018-03-12 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-03-27 to 2021-03-26

Registration No.: 50736-16-05

Ruth Delbeck-Bayer



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-03-12
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. 50736-16-05

Revision status: 0

Valid from 2018-03-27 to 2021-03-26

Devices/device categories included in the certificate:

Class II a:

- E-asy plus Introducer Sheath
- E-wire Guide Wire
- E-xpand Stent Graft Balloon Catheter

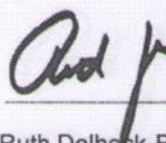
Class II b:

- FlowLine Bipore ePTFE Vascular graft
- E-njoy Peripheral Stent
- 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 TAA Stent Graft System / 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, 2018-03-12
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