

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
DEKRA Certification GmbH Stuttgart; 2018-03-12
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

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

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.



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