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 recertification audit report no. 50736-Z6-00, the decision dated 2021-03-24 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2021-03-24 to 2024-05-26

Registration No.: 50736-16-08

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2021-03-24
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

Annex to the EC Certificate No. 50736-16-08

Revision status: 0

Valid from 2021-03-24 to 2024-05-26

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
- E-vita thoracic 3G Stent Graft System
- E-vita open plus Stent Graft System
- E-tegra Stent Graft System
- E-nside TAAA Multibranch Stent Graft System
- E-nya Thoracic Stentgraft System
- E-vita OPEN NEO

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-03-24
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