CERTIFICATE

Digitally signed by Captari Alexandru
Date: 2019.02.07 16:23:28 EET
Reason: MoldSign Signature
Location: Moldova

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

DEKRA Certification GmbH Stuttgart Handwerkstraße 15

DEKRA

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

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

S.R.L. CAVATEH M.

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

DEKRA Certification GmbH * D-70565 Stuttgart, Handwerkstraße 15

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

S.R.L. CAVATEH M.

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

DEKRA Certification GmbH Stuttgart Handwerkstraße 15 D-70565 Stuttgart DEKRA

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

S.R.L. „CAVATEH M." IDNO 1012600031

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.

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2018-03-12
Notified Body ID-number: 0124

S.R.L. „CAVATEH M.“