CERTIFICATE

Digitally signed by Captari Alexandru
Date: 2020.01.22 13:06:13 EET
Reason: MoldSign Signature
Location: Moldova

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

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-03-27

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

84460

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:

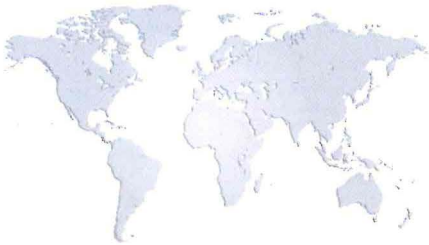
	Headquarters	Certified location	Scope of certification
	JOTEC GmbH	Lotzenäcker 23 D-72379 Hechingen	Development, manufacturing and distribution of medical devices for the treatment of vascular diseases. Manufacturing of Matricart and ePTFE tubes.
	Subsidiaries	**Certified locations**	**Scope of certification**
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	Etzental 64-4 D-72379 Hechingen	Preparation and testing of the yarns used in the knitting and weaving of vascular prostheses. Raw material warehouse.

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

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

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-03-27
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

84460

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.

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

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

84460

FlowWeave BIOSEAL

Woven vascular prostheses:

- Specific weaving techniques for high burst resistance and low dilatation[1,2]
- Different internal and external surface structures enable blood flow optimization
- Aldehyde and isocyanate free BIOSEAL impregnation using dehydrothermal crosslinked collagen guarantees primary sealing of the blood in the prosthesis[3]
- Concentric crimping and the guide line allow precise positioning of the prosthesis
- Soft and supple texture for easy handling

CryoLife®
Life Restoring Technologies®

JOTEC®
Joined the CryoLife® Family

PROSTHESIS REFERENCES

Catalogue No.	Ø (mm)	Length (cm)
45ST1508	8	15
45ST3008	8	30
45ST1510	10	15
45ST3010	10	30
45ST1512	12	15
45ST3012	12	30
45ST1520	20	15
45ST3020	20	30
45ST1522	22	15
45ST3022	22	30
45ST1524	24	15
45ST3024	24	30
45ST1526	26	15

Catalogue No.	Ø (mm)	Length (cm)
45ST3026	26	30
45ST1528	28	15
45ST3028	28	30
45ST1530	30	15
45ST3030	30	30
45ST1532	32	15
45ST3032	32	30
45ST1534	34	15
45ST3034	34	30

Ø
8-34 mm

Length
15-30 cm

References:

[1] *JOTEC GmbH, subsidiary of CryoLife, Inc.: Internal mechanical test data*

[2] *Bell C-M.: [Study on the issue of expansion of textile implants] - (internal data, JOTEC GmbH)*

[3] *Freischlag J, J.A. and Moore, W. S.: Clinical Experience with a Collagen-Impregnated Knitted Dacron Vascular Graft; Ann of Vascular Surg 1990; 4(5): 449-454*

Indications: FlowWeave BIOSEAL is indicated in arterial aneurysms and vascular occlusions. The primary indication for FlowWeave BIOSEAL is vascular replacement in the thoracic and abdominal aortas, although it can also be used in peripheral vascular applications involving vessel diameters of at least 6 mm.

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CryoLife, Inc.

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Madrid – Spain

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Warsaw – Poland

CryoLife Europa, Ltd.
Guildford – United Kingdom

JT-BR-0450200-EN V02 09/2018

CryoLife® Life Restoring Technologies®

JOTEC® Joined the CryoLife® Family