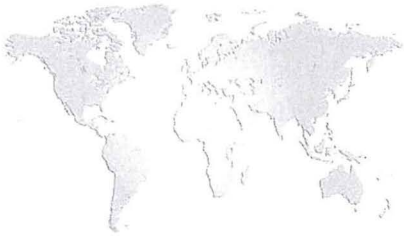
CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

JOTEC GmbH

Scope of certification:

Development, manufacturing, and distribution of medical devices for the treatment of vascular diseases.
Distribution of medical devices for the treatment of cardiovascular diseases.
Manufacturing of Matricart and Vascular Grafts.

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-Z6-00.

Certificate registration no.:	50736-14-01	Certificate valid from:	2021-03-27
Validity of previous certificate:	2021-03-26	Certificate valid to:	2024-03-26

DEKRA Certification GmbH Stuttgart Handwerkstraße 15

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

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

Digitally signed by Captari Alexandru
Date: 2021.09.04 13:29:34 EEST
Reason: MoldSign Signature
Location: Moldova

Annex to the Certificate No. 50736-14-01

Revision status: 0

valid from 2021-03-27 to 2024-03-26

The following locations / companies belong to the certificate above:

	Headquarter	Certified location	Scope of certification
	JOTEC GmbH	Lotzenäcker 23 72379 Hechingen Germany	Development, manufacturing, and distribution of medical devices for the treatment of vascular diseases. Distribution of medical devices for the treatment of cardiovascular diseases. Manufacturing of Matricart and Vascular Grafts.
	at the following locations / at the companies at the following locations		**Scope of certification**
1.	JOTEC GmbH	Lotzenäcker 25 72379 Hechingen Germany	Development, manufacturing, and distribution of medical devices for the treatment of vascular diseases. Manufacturing of stent springs. Storage of medical devices. Laboratories for quality control and microbiology.
2.	JOTEC GmbH	Im Etzental 64-4 72379 Hechingen Germany	Preparation and testing of yarns used in the knitting and weaving of vascular protheses. Raw materials warehouse

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

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 Certification

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 Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-03-24
Notified Body ID-number: 0124

JOTEC®

SOLUTIONS FOR VASCULAR DISEASE

Zertifikat - Certificate - Certificat

EC Declaration of Conformity

according to Annex II of the Medical Device Directive 93/42/EEC

We, the manufacturer **JOTEC GmbH**
Lotzenäcker 23
72379 Hechingen, Germany

herewith declare under sole responsibility that the medical device

FlowNit
FlowNit Bioseal
FlowWeave
FlowWeave Bioseal

Textile Vascular Graft
Class III-product according to 93/42/EEC,
Annex IX, Rule 8

with the CE-marking CE 0124

is in accordance with all requirements of the Medical Device Directive 93/42/EEC which are applicable. (Annex with catalogue numbers attached)

This declaration was issued based on EC Design Examination Certificate dated 24.03.2017 (Certificate-registration No. 50736-53-A5).

Notified Body according to Annex XI of the Medical Device Directive is:
DEKRA Certification GmbH, Handwerkstr. 15, 70565 Stuttgart, Germany,
ID No. 0124

Date of the first declaration:	29.10.2004	Date of redeclaration:	27.03.2017
This declaration is valid until	26-03-2022		

Thomas Bogenschütz
CEO
JOTEC GmbH
Hechingen, 27.03.2017

Steffen Rauschenberger
QA/RA Director

JOTEC®

SOLUTIONS FOR VASCULAR DISEASE

Annex to the EC Declaration of Conformity for the medical device FlowNit, FlowNit Bioseal, FlowWeave, FlowWeave Bioseal

Product nomenclature:

35ST1506	**Product group** 30 = FlowNit 35 = FlowNit Bioseal 40 = FlowWeave 45 = FlowWeave Bioseal
35**ST**1506	**Configuration** ST = Straight tube BI = Bifurcation (only FlowNit / FlowNit Bioseal))
35ST**15**06	For ST: **Length [cm]** (100cm = 00) For BI: **Diameter body [mm]**
35ST15**06**	For ST = **Diameter [mm]** For BI = **Diameter legs [mm]**

Variations:

Variations result from the configuration (straight tubes / bifurcations), length and diameter.

Tubes:	
Length	15 cm – 100 cm
Diameter	6 mm – 38 mm

Bifurcations:	
Length	45 cm
Diameter ($Ø_{body}$ x $Ø_{legs}$):	12 mm x 6 mm – 24 mm x 12 mm

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

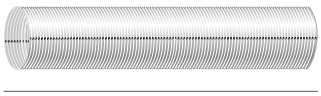
CryoLife®
Life Restoring Technologies®

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.

JOTEC GmbH,
a fully owned subsidiary of
CryoLife, Inc.

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Milan – Italy

JOTEC Cardiovascular SL
Madrid – Spain

JOTEC Polska Sp. z o.o.
Warsaw – Poland

CryoLife Europa, Ltd.
Guildford – United Kingdom

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