CERTIFICATE

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)

Digitally signed by Captari Alexandru
Date: 2021.03.16 14:28:12 EET
Reason: MoldSign Signature
Location: Moldova

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:

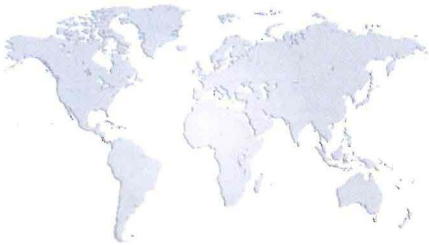
	Headquarters	Certified location	Scope of certification
	JOTEC GmbH	Lotzenäcker 23 D-72379 Hechingen	Development, manufacturing and distribution of medical devices for the treatment of vascular diseases. Manufacturing of Matricart and ePTFE tubes.
	Subsidiaries	**Certified locations**	**Scope of certification**
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

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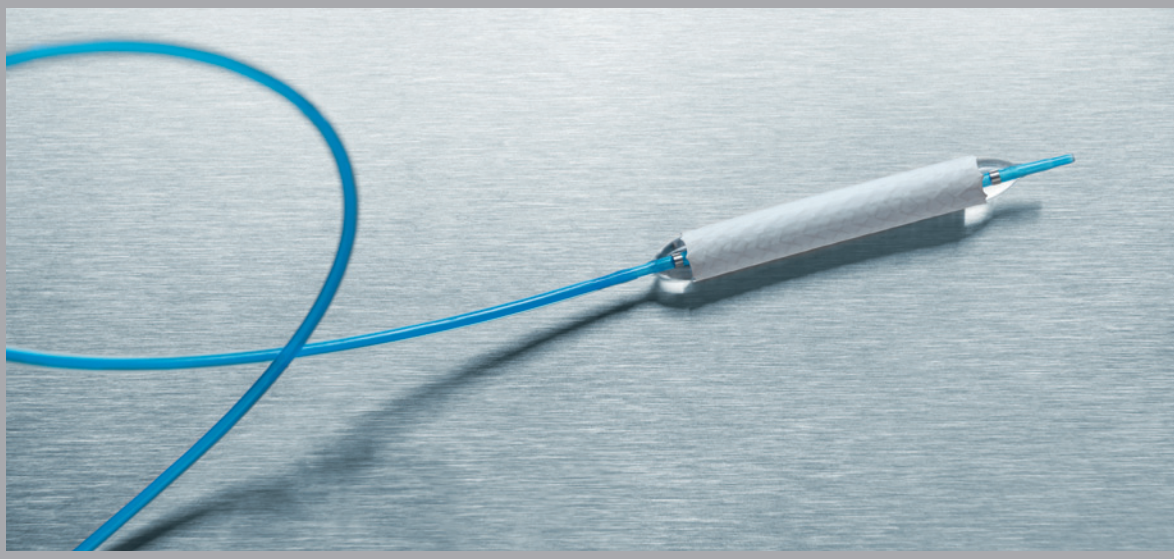
JOTEC®



e-ventus® BX

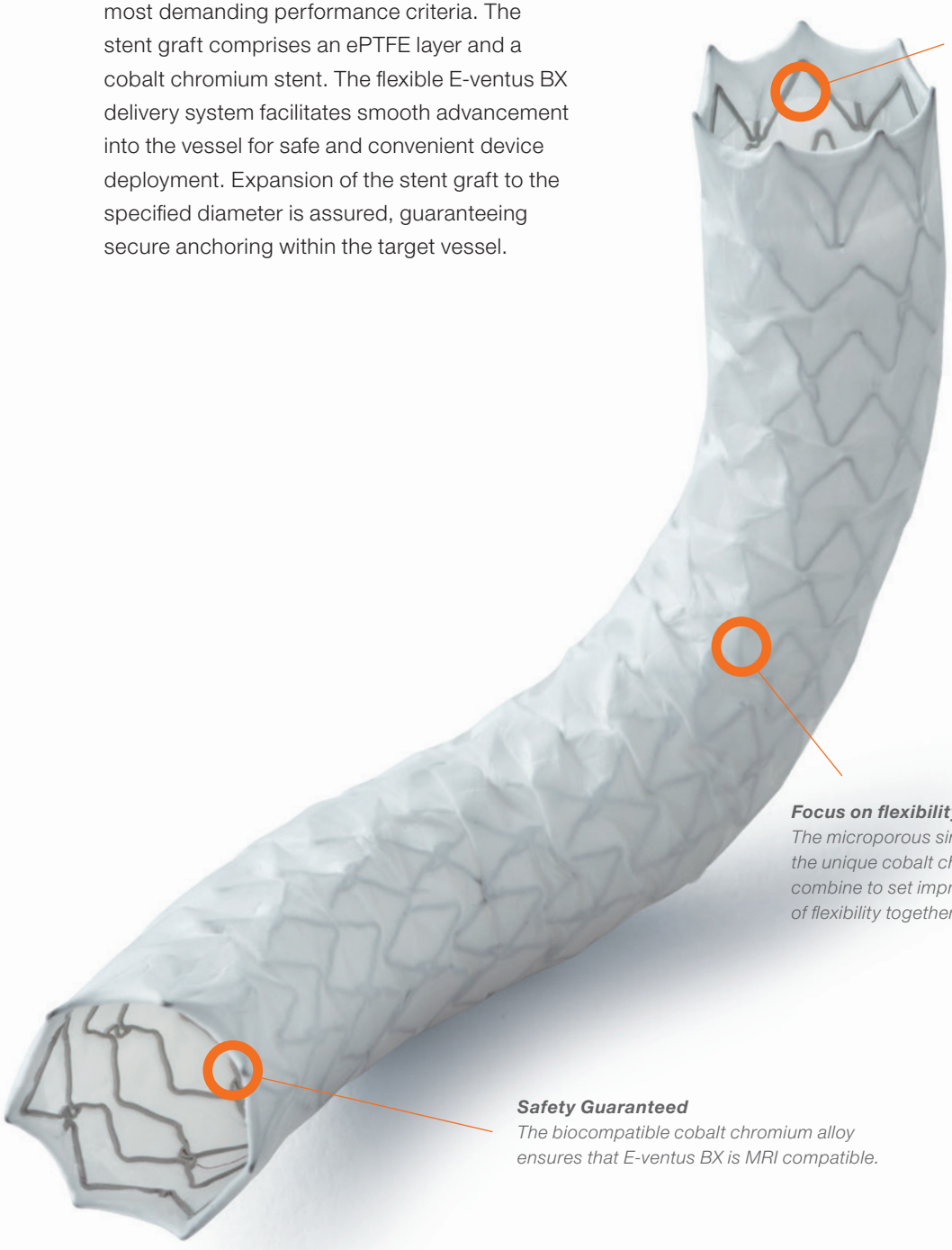
Peripheral Stent Graft System

SOLUTIONS FOR VASCULAR DISEASE

PURE PERFORMANCE AND QUALITY: JOTEC STENT GRAFT SYSTEMS

E-ventus BX is another advanced product from JOTEC for the endovascular treatment of peripheral vascular disease. E-ventus BX is a balloon-expandable peripheral stent graft indicated for interventional therapy of renal and iliac arteries in cases such as ruptures, dissections and aneurysms.

The unique design of E-ventus BX satisfies the most demanding performance criteria. The stent graft comprises an ePTFE layer and a cobalt chromium stent. The flexible E-ventus BX delivery system facilitates smooth advancement into the vessel for safe and convenient device deployment. Expansion of the stent graft to the specified diameter is assured, guaranteeing secure anchoring within the target vessel.



Pure Precision
The E-ventus BX stent graft features minimal recoil and foreshortening during and after expansion.

Focus on flexibility
The microporous single-layer ePTFE and the unique cobalt chromium stent design combine to set impressive new standards of flexibility together with high radial strength.

Safety Guaranteed
The biocompatible cobalt chromium alloy ensures that E-ventus BX is MRI compatible.

Design and functionality – in perfect harmony

Every detail is carefully thought-out:

- Stent graft diameters from 5 to 10 mm and lengths from 18 to 58 mm provide for the treatment of a wide range of vascular anatomies
- Low profile delivery systems facilitate vessel access:
  -6 F for 5 and 6 mm stent grafts
  -7 F for 7 to 10 mm stent grafts
- Highly flexible delivery catheter ensures good trackability and that the target lesion is reached safely and conveniently
- X-ray markers on the delivery system provide clear visualisation of the stent graft allowing confident and accurate positioning

Stent graft compliance:

Inflation Pressure (bar)	Stent Outer Diameter (mm)					
	ø 5.0	ø 6.0	ø 7.0	ø 8.0	ø 9.0	ø 10.0
8				8.0	9.0	10.0
9	5.0	6.0	7.0	8.3	9.2	10.2
10	5.2	6.2	7.2	8.5	9.4	10.4
11	5.3	6.4	7.3	8.7	9.6	10.6
12	5.4	6.5	7.5	8.8	9.7	10.7
13	5.5	6.6	7.6			

NP Nominal Pressure

RBP Rated Burst Pressure

Product overview and order information

Catalogue-No.	Crimped stent length (mm)	Expanded stent diameter (mm)	Required introducer sheath (F)	Working catheter length (cm)
91BX1805L-00	18	5.0	6	120
91BX2205L-00	22	5.0	6	120
91BX2805L-00	28	5.0	6	120
91BX3805L-00	38	5.0	6	120
91BX5805L-00	58	5.0	6	120
91BX1806L-00	18	6.0	6	120
91BX2206L-00	22	6.0	6	120
91BX2806L-00	28	6.0	6	120
91BX3806L-00	38	6.0	6	120
91BX5806L-00	58	6.0	6	120
91BX1807L-00	18	7.0	7	120
91BX2307L-00	23	7.0	7	120

Catalogue-No.	Crimped stent length (mm)	Expanded stent diameter (mm)	Required introducer sheath (F)	Working catheter length (cm)
91BX2707L-00	27	7.0	7	120
91BX3707L-00	37	7.0	7	120
91BX5707L-00	57	7.0	7	120
91BX2708L-00	27	8.0	7	120
91BX3708L-00	37	8.0	7	120
91BX5708L-00	57	8.0	7	120
91BX2709L-00	27	9.0	7	120
91BX3709L-00	37	9.0	7	120
91BX5709L-00	57	9.0	7	120
91BX2710L-00	27	10.0	7	120
91BX3710L-00	37	10.0	7	120
91BX5710L-00	57	10.0	7	120

75 cm working catheter length are available on request

JOTEC®

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