EC Design Examination Certificate

according the directive 93/42/EEC, Annex II (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies for the manufacturer

JOTEC GmbH
Lotzenäcker 23, 72379 Hechingen, Germany

that the design dossier for the product(s) described in the annex complies with the requirements of the directive 93/42/EEC. This certificate is based on the result of the examination of the design dossier according to the directive 93/42/EEC Annex II.4 as documented in the report mentioned in the annex.

Product: E-tegra Stent Graft System

This certificate is valid from 2019-11-12 to 2024-05-26

Registration No.: 50736-23-J1

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-11-08
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

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Annex to the EC Design Examination Certificate No. 50736-23-J1

Revision status: 1

Valid from 2019-11-21 to 2024-05-26

Report number: 50736-P10-02

Product: E-tegra Stent Graft System

Intended use:

The E-tegra Stent Graft System is indicated for the endovascular treatment of infrarenal aortic aneurysms. These aneurysms can also affect the arteria iliaca.

Technical data:

The E-tegra Stent Graft System contents of a delivery system with preloaded stent graft components: Bifurcation Main Prosthesis (MB), Monoiliac Main Prosthesis (AU); Aortic Extension (AE), Contralateral Leg (CL), Iliacal Extension (IE).

Implant					
Textile / Fabric:	PET (Polyester)				
Stent:	Nitinol, laser cut				
Productcode	XX min - max [mm]	YY min - max [mm]	AA min - max [cm]	BB min -max [cm]	EFS Größe [F]
93MBXXYYLAA-BB	23-36	10-22	10-17	08-10	18 & 20
93AUXXYYLAA	23-36	13	11	n/a	18 & 20
93AEXXYYLAA	23-38	23-38	05	n/a	18 & 20
93CLXXYYLAA	15	10-25	03-10,5	n/a	16
93IEXXYYLAA	13-27	10-27	05	n/a	18 & 20

Delivery System	
Aortal Stent Graft Components (MB, AU, AE)	Diameter 18F, 20F Usable Length 550 mm, Guide Wire = 0.035"
Iliacal Stent Graft Components (CL, IE)	Diameter 16F, 18F Usable Length 550 mm, Guide Wire = 0.035"

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