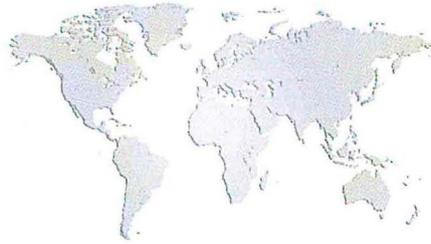


# EC Design Examination Certificate



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





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](http://www.zlg.de)  
**ZLG-BS-295.10.02**

# 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:

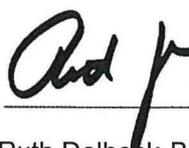
The E-tegra Stent Graft System is indicated for the endovascular treatment of infrarenal aortic aneurysms. These aneurysms can also affect the arteria iliaca.

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
93AEXYYLAA	23-38	23-38	05	n/a	18 & 20
93CLXXYYLAA	15	10-25	03-10,5	n/a	16
93IEXYYLAA	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"


Ruth Delbeck-Bayer  
DEKRA Certification GmbH, Stuttgart, 2019-11-21  
Notified Body ID-number: 0124

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* www.dekra-certification.de