

EC Design- Examination Certificate



**according to 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-vita open plus Stent Graft System

This certificate is valid from 2017-03-27 to 2022-03-26

Certificate registration No.: 50736-23-H5

DEKRA Certification GmbH Stuttgart; 2017-03-23

Notified Body ID-number: 0124

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Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-296.10.01

Annex to the EC design examination certificate 50736-23-H5 dated 2017-03-23

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Report number: 50736-P8-07

Product: E-vita open plus Stent Graft System

Intended use:

The E-vita open plus Stent Graft system is indicated for the treatment of aneurysms, dissections and specific lesions of the aorta descendens.

Technical data:

Delivery system

Diameter of the delivery system catheter [F]	Diameter of the Stent Graft [mm]
36	20 – 33
48	36 – 40

Stent Graft without collar

71ACXXYYSSZZ-PL

71ACXXYYSSOZZ-PL

71ACXXYYSTZZ-PL

71SOXXYYSSOZZ-00

71SOXXYYSTZZ-00

71SOXXYYSSZZ-00

71STXXYYSSOZZ-00

71STXXYYSTZZ-00

71STXXYYSSZZ-00

with

XX: Proximal diameter: 20 mm – 40 mm

YY: Distal diameter: 20 mm – 40 mm

ZZ: Covered length: 80 mm – 240 mm

AC: Aortic Cuff

SO: Straight Open

ST: Twin Stent

S: Straight Cut

Diameter cuff: 20 mm – 40 mm

Length cuff: 10 mm – 150 mm

Stent Graft with collar

71ACXXYYSSZZ-PL-CO

71ACXXYYSSOZZ-PL-CO

71ACXXYYSTZZ-PL-CO

71ACXXYYSSZZ-PL-CO-vv

with

XX: Proximal diameter: 20 mm – 40 mm

YY: Distal diameter: 20 mm – 40 mm

ZZ: Covered length: 80 mm – 240 mm

AC: Aortic Cuff

SO: Straight Open

ST: Twin Stent

S: Straight Cut

vv: Length cuff [cm]

Diameter cuff: 20 mm – 40 mm

Length cuff: 10 mm – 150 mm

Width collar: 02 mm – 40 mm