

# 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-vita OPEN NEO

This certificate is valid from 2020-03-19 to 2024-05-26

Registration No.: 50736-23-M1

A handwritten signature in black ink, appearing to read 'Ruth Delbeck-Bayer', positioned over the DEKRA logo.



Ruth Delbeck-Bayer  
DEKRA Certification GmbH Stuttgart; 2020-03-19  
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-M1

Revision status: 0

Valid from 2020-03-19 to 2024-05-26

Report number: 50736-P13-00

Product: E-vita OPEN NEO

Intended use:

E-vita OPEN NEO is intended for the surgical treatment of dissections or aneurysms of the thoracic aorta.

Technical data:

E-vita OPEN NEO Trifurcated Graft Configuration

Diameter vascular graft part	Diameter stent graft part	Length stent graft part	Length vascular graft part
26 mm	20 mm	175 mm	length without tension 100 mm
	22 mm		
	24 mm		
	26 mm		
28 mm	28 mm	180 mm	
30 mm	30 mm		
	33 mm		
	36 mm		
	40 mm		
<b>Diameter Branch LSA (left subclavian artery)</b>		10 mm	
<b>Diameter Branch LCA (left carotid artery)</b>		8 mm	
<b>Diameter Branch BCT (brachiocephalic trunk artery)</b>		12 mm	
<b>Diameter perfusion branch</b>		10 mm	
<b>Length of branches</b>		length without tension 100mm	
<b>Collar</b>		+30 mm to diameter of vascular graft part	
<b>Radiopaque marker</b>		1 ring marker proximal stent graft part 1 ring marker distal stent graft part 1 overlap marker	

E-vita OPEN NEO Branched Graft Configuration

Diameter vascular graft part	Diameter stent graft part	Length stent graft part (both length available)	Length vascular graft part
26 mm	20 mm	120 mm or 175 mm	length without tension 100 mm
	22 mm		
	24 mm		
	26 mm		
28 mm	28 mm	120 mm or 180 mm	
30 mm	30 mm		
	33 mm		
	36 mm		
	40 mm		
		130 mm or 180 mm	

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<b>Diameter Branch LSA</b> (left subclavian artery)	10 mm
<b>Diameter Branch LCA</b> (left carotid artery)	8 mm
<b>Diameter Branch BCT</b> (brachiocephalic trunk artery)	12 mm
<b>Diameter perfusion branch</b>	10 mm
<b>Length of branches</b>	length without tension 100 mm
<b>Collar</b>	+30 mm to diameter of vascular graft part
<b>Radiopaque marker</b>	1 ring marker proximal stent graft part 1 ring marker distal stent graft part 1 overlap marker

## E-vita OPEN NEO Straight Graft Configuration

<b>Diameter vascular graft part</b>	<b>Diameter stent graft part</b>	<b>Length stent graft part (both length available)</b>	<b>Length vascular graft part</b>
26 mm	20 mm	120 mm or 175 mm	length without tension 100 mm
	22 mm		
	24 mm		
	26 mm	120 mm or 180 mm	
28 mm	28 mm	130 mm or 180 mm	
30 mm	30 mm		
	33 mm		
	36 mm		
	40 mm		
<b>Diameter perfusion branch</b>		10 mm	
<b>Length of perfusion branch</b>		length without tension 100 mm	
<b>Collar</b>		+30 mm to diameter of vascular graft part	
<b>radiopaque marker</b>		1 ring marker proximal stent graft part 1 ring marker distal stent graft part 1 overlap marker	

*Ruth Delbeck-Bayer*



Ruth Delbeck-Bayer  
DEKRA Certification GmbH, Stuttgart, 2020-03-19  
Notified Body ID-number: 0124