

EC Design Examination Certificate

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the design of the medical device(s)

BeGraft Aortic Stent Graft System

with specifications listed in the appendix

of the manufacturer

Bentley InnoMed GmbH
Lotzenäcker 3
72379 Hechingen
Germany

Fulfills the below mentioned requirements of the **Council Directive 93/42/EEC**:

Annex II, section 4

This certificate assumes that MEDCERT has to be informed about any changes of the approved design. Changes need further approval by MEDCERT.

For the placing on the market of medical devices covered by this certificate, a separate EC certificate of conformity according to Annex II without section 4 of Council Directive 93/42/EEC is required.

Effective date: 2020-06-05

Expiry date: 2024-05-27

Report No.: 13851FS02F

Process No.: PP – 13851

Certificate No.: 13851GB411200605

Hamburg, 2020-06-05



MEDCERT Certification Body
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

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Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Design Examination Certificate

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Specifications

BeGraft Aortic Stent Graft System						
BGA1912 _1	BGA1914 _1	BGA1916 _1	n.a.	n.a.	n.a.	n.a.
BGA1912 _2	BGA1914 _2	BGA1916 _2	n.a.	n.a.	n.a.	n.a.
BGA2912 _1	BGA2914 _1	BGA2916 _1	n.a.	n.a.	n.a.	n.a.
BGA2912 _2	BGA2914 _2	BGA2916 _2	BGA2918 _2	BGA2720 _2	n.a.	n.a.
BGA3912 _1	BGA3914 _1	BGA3816 _1	n.a.	n.a.	n.a.	n.a.
BGA3912 _2	BGA3914 _2	BGA3816 _2	BGA3818 _2	BGA3720 _2	BGA3722 _2	BGA3724 _2
BGA4912 _1	BGA4914 _1	BGA4816 _1	n.a.	n.a.	n.a.	n.a.
BGA4912 _2	BGA4914 _2	BGA4816 _2	BGA4818 _2	BGA4820 _2	BGA4822 _2	BGA4824 _2
BGA5912 _1	BGA5914 _1	BGA5816 _1	n.a.	n.a.	n.a.	n.a.
BGA5912 _2	BGA5914 _2	BGA5816 _2	n.a.	n.a.	n.a.	n.a.

– End of list –

This appendix is integral part of the above-referenced certificate.
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