

BIOTECH GmbH	Biotech Pectus Bar Correct System	v03
EC – Declaration of Conformity for Medical Products		

based on the 93/42 EEC Directive for Medical Products amended by 2007/47/EC

Manufacturer:

Biotech GmbH

Hagenauer Str. 17-19,
65203 Wiesbaden;
Germany

We declare by our own responsibility that the product group

Article description:

Biotech Pectus Bar Correct System

Implant Article Numbers: see on page 2-3.

(UMDNS Code)

13-049

Classification:

Class II.b.

Comply with the essential requirements of Annex I of Directive 93/42/EEC as amended by 2007/47 IEC.

This Declaration is supported by the EC Certificate Full Quality Assurance System (Directive 93/42/EEC on Medical Devices, Annex II excluding (4) by:

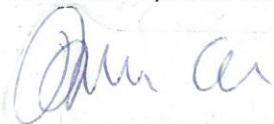
National Institute of Pharmacy and Nutrition, Directorate of Device Testing and Clinical Engineering (EMKI) H-1051 Budapest, Zrínyi u. 3.

Notify Body identification number: 1011

Certificate number: 5-657-200-1008

Date of issue: 10.08.2010

Wiesbaden, 16.09.2017



Dr. Alkaysi Ghazi
General Director

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Company stamp

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Article No.	Description	Size	Material
113-7070-0000	Pectus Bar Implant	length: 18,0 cm	Stainless steel
113-7080-0000	Pectus Bar Implant	length: 20,5 cm	Stainless steel
113-7090-0000	Pectus Bar Implant	length: 23,0 cm	Stainless steel
113-7100-0000	Pectus Bar Implant	length: 25,5 cm	Stainless steel
113-7110-0000	Pectus Bar Implant	length: 28,0 cm	Stainless steel
113-7120-0000	Pectus Bar Implant	length: 30,5 cm	Stainless steel
113-7130-0000	Pectus Bar Implant	length: 33,0 cm	Stainless steel
113-7140-0000	Pectus Bar Implant	length: 35,5 cm	Stainless steel
113-7150-0000	Pectus Bar Implant	length: 38,0 cm	Stainless steel
113-7160-0000	Pectus Bar Implant	length: 40,5 cm	Stainless steel
113-7170-0000	Pectus Bar Implant	length: 43,0 cm	Stainless steel
113-7180-0000	Pectus Bar Implant	length: 45,5 cm	Stainless steel
113-8010-0000	Pectus Bar stabilisator plate	long	Stainless steel
113-8020-0000	Pectus Bar stabilisator plate	short	Stainless steel
113-8030-0000	Pectus Bar stabilisator plate	fixed	Stainless steel
113-8040-0000	fixation screw for fixed stabilisator plate		Stainless steel 316LVM
213-7070-0000	Pectus Bar Implant	length: 18,0 cm	TiAl6V4
213-7080-0000	Pectus Bar Implant	length: 20,5 cm	TiAl6V4
213-7090-0000	Pectus Bar Implant	length: 23,0 cm	TiAl6V4
213-7100-0000	Pectus Bar Implant	length: 25,5 cm	TiAl6V4
213-7110-0000	Pectus Bar Implant	length: 28,0 cm	TiAl6V4
213-7120-0000	Pectus Bar Implant	length: 30,5 cm	TiAl6V4
213-7130-0000	Pectus Bar Implant	length: 33,0 cm	TiAl6V4
213-7140-0000	Pectus Bar Implant	length: 35,5 cm	TiAl6V4
213-7150-0000	Pectus Bar Implant	length: 38,0 cm	TiAl6V4
213-7160-0000	Pectus Bar Implant	length: 40,5 cm	TiAl6V4
213-7170-0000	Pectus Bar Implant	length: 43,0 cm	TiAl6V4
213-7180-0000	Pectus Bar Implant	length: 45,5 cm	TiAl6V4
213-8010-0000	Pectus Bar stabilisator plate	long	TiAl6V4
213-8020-0000	Pectus Bar stabilisator plate	short	TiAl6V4
213-8030-0000	Pectus Bar stabilisator plate	fixed	TiAl6V4
213-8040-0000	fixation screw for fixed stabilisator plate		TiAl6V4
313-8010-0000	Pectus Bar stabilisator plate	long	CoCr
313-8020-0000	Pectus Bar stabilisator plate	short	CoCr
313-8030-0000	Pectus Bar stabilisator plate	fixed	CoCr
S113-7070-0000	Pectus Bar Implant, sterile	length: 18,0 cm	Stainless steel
S113-7080-0000	Pectus Bar Implant, sterile	length: 20,5 cm	Stainless steel
S113-7090-0000	Pectus Bar Implant, sterile	length: 23,0 cm	Stainless steel
S113-7100-0000	Pectus Bar Implant, sterile	length: 25,5 cm	Stainless steel
S113-7110-0000	Pectus Bar Implant, sterile	length: 28,0 cm	Stainless steel
S113-7120-0000	Pectus Bar Implant, sterile	length: 30,5 cm	Stainless steel
S113-7130-0000	Pectus Bar Implant, sterile	length: 33,0 cm	Stainless steel

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S113-7140-0000	Pectus Bar Implant, sterile	length: 35,5 cm	Stainless steel
S113-7150-0000	Pectus Bar Implant, sterile	length: 38,0 cm	Stainless steel
S113-7160-0000	Pectus Bar Implant, sterile	length: 40,5 cm	Stainless steel
S113-7170-0000	Pectus Bar Implant, sterile	length: 43,0 cm	Stainless steel
S113-7180-0000	Pectus Bar Implant, sterile	length: 45,5 cm	Stainless steel
S113-8010-0000	Pectus Bar stabilisator plate, sterile	long	Stainless steel
S113-8020-0000	Pectus Bar stabilisator plate, sterile	short	Stainless steel
S113-8030-0000	Pectus Bar stabilisator plate, sterile	fixed	Stainless steel
S213-7070-0000	Pectus Bar Implant, sterile	length: 18,0 cm	TiAl6V4
S213-7080-0000	Pectus Bar Implant, sterile	length: 20,5 cm	TiAl6V4
S213-7090-0000	Pectus Bar Implant, sterile	length: 23,0 cm	TiAl6V4
S213-7100-0000	Pectus Bar Implant, sterile	length: 25,5 cm	TiAl6V4
S213-7110-0000	Pectus Bar Implant, sterile	length: 28,0 cm	TiAl6V4
S213-7120-0000	Pectus Bar Implant, sterile	length: 30,5 cm	TiAl6V4
S213-7130-0000	Pectus Bar Implant, sterile	length: 33,0 cm	TiAl6V4
S213-7140-0000	Pectus Bar Implant, sterile	length: 35,5 cm	TiAl6V4
S213-7150-0000	Pectus Bar Implant, sterile	length: 38,0 cm	TiAl6V4
S213-7160-0000	Pectus Bar Implant, sterile	length: 40,5 cm	TiAl6V4
S213-7170-0000	Pectus Bar Implant, sterile	length: 43,0 cm	TiAl6V4
S213-7180-0000	Pectus Bar Implant, sterile	length: 45,5 cm	TiAl6V4
S213-8010-0000	Pectus Bar stabilisator plate, sterile	long	TiAl6V4
S213-8020-0000	Pectus Bar stabilisator plate, sterile	short	TiAl6V4
S213-8030-0000	Pectus Bar stabilisator plate, sterile	fixed	TiAl6V4
S313-8010-0000	Pectus Bar stabilisator plate, sterile	long	CoCr
S313-8020-0000	Pectus Bar stabilisator plate, sterile	short	CoCr
S313-8030-0000	Pectus Bar stabilisator plate, sterile	fixed	CoCr



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