

BIOTECH GmbH Hauptstraße 113. 56598 Rheinbrohl Germany	BIOTECH GmbH Branch office in Hungary 2049 Diósd, Petőfi S. u. 43-47. Hungary	EC – Declaration of Conformity for Implants of „Biotech Pectus Bar Correct System”	
Document ID:	Version:	Document releasing date:	Page Number/ Number of Page(s):
DoC-CE-PE-D-CL-IIb-DCL	v05	01.04.2022	1 / 1

Manufacturer: **Biotech GmbH**
Hauptstraße 113.
56598 Rheinbrohl Germany

We declare by our own responsibility that the product group (see detailed list below in Article description):
“Biotech Pectus Bar Correct System”

Complies with the essential requirements of Annex I of Directive 93/42/EEC as amended by 2007/47/EC.
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 Medical Device Conformity Assessment and Certification LLC (NEOEMKI)

H- 1097 Budapest, Albert Flórián út 3/a. - Notify Body identification number: **1011**

Certificate number: **5-903-200-2103** - Date of first issue: **09.03.2021**- Date of validation: **26.05.2024**



Article description:

Implant medical devices:

Biotech Pectus Bar Correct System

Implant Article Numbers:

see **Annex No. 01** of EC – Declaration of Conformity for Implants of “Biotech Pectus Bar Correct System”

(Doc ID: DoC-CE-PE-D-CL-IIb-ANX-01)

Declaration:

The devices have not contain medicinal products, tissues of animal origin, human blood and human blood derivatives.

UMDNS code:

13-049; 16-101

Classification:

Class II.b

This declaration is valid for the products placed on the market after **01.04.2022**

Rheinbrohl, 01.04.2022

Dr. Alkaysi Ghazi
General Director
Biotech GmbH

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Company stamp

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Medical Devices – Implant Article Numbers /Class IIb/ – Biotech Pectus Bar Correct System

NO.	Medical Device - Implant Class IIb					
	REFERENCE NUMBER	GTIN CODE	DESCRIPTION	SIZE (TYPE)	TYPE OF CE MARK	MATERIAL
1	113-6880-0000	4049852000550	Pectus Bar Implant	length: 8,0 cm	CE1011	Stainless steel
2	113-6900-0000	4049852000567	Pectus Bar Implant	length: 9,0 cm	CE1011	Stainless steel
3	113-6920-0000	4049852000574	Pectus Bar Implant	length: 10,0 cm	CE1011	Stainless steel
4	113-6930-0000	4049852000581	Pectus Bar Implant	length: 10,5 cm	CE1011	Stainless steel
5	113-6940-0000	4049852000598	Pectus Bar Implant	length: 11,0 cm	CE1011	Stainless steel
6	113-6950-0000	4049852000604	Pectus Bar Implant	length: 11,5 cm	CE1011	Stainless steel
7	113-6960-0000	4049852000611	Pectus Bar Implant	length: 12,0 cm	CE1011	Stainless steel
8	113-6970-0000	4049852000628	Pectus Bar Implant	length: 12,5 cm	CE1011	Stainless steel
9	113-6980-0000	4049852000635	Pectus Bar Implant	length: 13,0 cm	CE1011	Stainless steel
10	113-6990-0000	4049852000642	Pectus Bar Implant	length: 13,5 cm	CE1011	Stainless steel

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NO.	Medical Device - Implant Class IIb					
	REFERENCE NUMBER	GTIN CODE	DESCRIPTION	SIZE (TYPE)	TYPE OF CE MARK	MATERIAL
11	113-7000-0000	4049852000659	Pectus Bar Implant	length: 14,0 cm	CE1011	Stainless steel
12	113-7010-0000	4049852000666	Pectus Bar Implant	length: 14,5 cm	CE1011	Stainless steel
13	113-7020-0000	4049852000673	Pectus Bar Implant	length: 15,0 cm	CE1011	Stainless steel
14	113-7030-0000	4049852000680	Pectus Bar Implant	length: 15,5 cm	CE1011	Stainless steel
15	113-7040-0000	4049852000697	Pectus Bar Implant	length: 16,0 cm	CE1011	Stainless steel
16	113-7050-0000	4049852000703	Pectus Bar Implant	length: 16,5 cm	CE1011	Stainless steel
17	113-7060-0000	4049852000710	Pectus Bar Implant	length: 17,0 cm	CE1011	Stainless steel
18	113-7070-0000	4049852016933	Pectus Bar Implant	length: 18,0 cm	CE1011	Stainless steel
19	113-7080-0000	4049852004978	Pectus Bar Implant	length: 20,5 cm	CE1011	Stainless steel
20	113-7090-0000	4049852004985	Pectus Bar Implant	length: 23,0 cm	CE1011	Stainless steel
21	113-7100-0000	4049852004992	Pectus Bar Implant	length: 25,5 cm	CE1011	Stainless steel

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NO.	Medical Device - Implant Class IIb					
	REFERENCE NUMBER	GTIN CODE	DESCRIPTION	SIZE (TYPE)	TYPE OF CE MARK	MATERIAL
22	113-7110-0000	4049852005005	Pectus Bar Implant	length: 28,0 cm	CE1011	Stainless steel
23	113-7120-0000	4049852005012	Pectus Bar Implant	length: 30,5 cm	CE1011	Stainless steel
24	113-7130-0000	4049852005029	Pectus Bar Implant	length: 33,0 cm	CE1011	Stainless steel
25	113-7140-0000	4049852005036	Pectus Bar Implant	length: 35,5 cm	CE1011	Stainless steel
26	113-7150-0000	4049852005043	Pectus Bar Implant	length: 38,0 cm	CE1011	Stainless steel
27	113-7160-0000	4049852005050	Pectus Bar Implant	length: 40,5 cm	CE1011	Stainless steel
28	113-7170-0000	4049852005067	Pectus Bar Implant	length: 43,0 cm	CE1011	Stainless steel
29	113-7180-0000	4049852005074	Pectus Bar Implant	length: 45,5 cm	CE1011	Stainless steel
30	113-8010-0000	4049852005081	Pectus Bar stabilisator plate	long	CE1011	Stainless steel
31	113-8020-0000	4049852113205	Pectus Bar stabilisator plate	short	CE1011	Stainless steel
32	113-8030-0000	4049852016940	Pectus Bar stabilisator plate	fixed	CE1011	Stainless steel

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NO.	Medical Device - Implant Class IIb					
	REFERENCE NUMBER	GTIN CODE	DESCRIPTION	SIZE (TYPE)	TYPE OF CE MARK	MATERIAL
33	113-8040-0000	4049852139830	fixation screw for fixed stabilisator plate	–	CE1011	Stainless steel
34	213-6880-0000	4049852000727	Pectus Bar Implant	length: 8,0 cm	CE1011	Ti6Al4V
35	213-6900-0000	4049852000734	Pectus Bar Implant	length: 9,0 cm	CE1011	Ti6Al4V
36	213-6920-0000	4049852000741	Pectus Bar Implant	length: 10,0 cm	CE1011	Ti6Al4V
37	213-6930-0000	4049852000758	Pectus Bar Implant	length: 10,5 cm	CE1011	Ti6Al4V
38	213-6940-0000	4049852000765	Pectus Bar Implant	length: 11,0 cm	CE1011	Ti6Al4V
39	213-6950-0000	4049852000772	Pectus Bar Implant	length: 11,5 cm	CE1011	Ti6Al4V
40	213-6960-0000	4049852000789	Pectus Bar Implant	length: 12,0 cm	CE1011	Ti6Al4V
41	213-6970-0000	4049852000796	Pectus Bar Implant	length: 12,5 cm	CE1011	Ti6Al4V
42	213-6980-0000	4049852000802	Pectus Bar Implant	length: 13,0 cm	CE1011	Ti6Al4V
43	213-6990-0000	4049852000819	Pectus Bar Implant	length: 13,5 cm	CE1011	Ti6Al4V

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NO.	Medical Device - Implant Class IIb					
	REFERENCE NUMBER	GTIN CODE	DESCRIPTION	SIZE (TYPE)	TYPE OF CE MARK	MATERIAL
44	213-7000-0000	4049852000826	Pectus Bar Implant	length: 14,0 cm	CE1011	Ti6Al4V
45	213-7010-0000	4049852000833	Pectus Bar Implant	length: 14,5 cm	CE1011	Ti6Al4V
46	213-7020-0000	4049852000840	Pectus Bar Implant	length: 15,0 cm	CE1011	Ti6Al4V
47	213-7030-0000	4049852000901	Pectus Bar Implant	length: 15,5 cm	CE1011	Ti6Al4V
48	213-7040-0000	4049852000918	Pectus Bar Implant	length: 16,0 cm	CE1011	Ti6Al4V
49	213-7050-0000	4049852000925	Pectus Bar Implant	length: 16,5 cm	CE1011	Ti6Al4V
50	213-7060-0000	4049852000932	Pectus Bar Implant	length: 17,0 cm	CE1011	Ti6Al4V
51	213-7070-0000	4049852016957	Pectus Bar Implant	length: 18,0 cm	CE1011	Ti6Al4V
52	213-7080-0000	4049852016964	Pectus Bar Implant	length: 20,5 cm	CE1011	Ti6Al4V
53	213-7090-0000	4049852016971	Pectus Bar Implant	length: 23,0 cm	CE1011	Ti6Al4V
54	213-7100-0000	4049852016988	Pectus Bar Implant	length: 25,5 cm	CE1011	Ti6Al4V

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NO.	Medical Device - Implant Class IIb					
	REFERENCE NUMBER	GTIN CODE	DESCRIPTION	SIZE (TYPE)	TYPE OF CE MARK	MATERIAL
55	213-7110-0000	4049852016995	Pectus Bar Implant	length: 28,0 cm	CE1011	Ti6Al4V
56	213-7120-0000	4049852017008	Pectus Bar Implant	length: 30,5 cm	CE1011	Ti6Al4V
57	213-7130-0000	4049852017015	Pectus Bar Implant	length: 33,0 cm	CE1011	Ti6Al4V
58	213-7140-0000	4049852017022	Pectus Bar Implant	length: 35,5 cm	CE1011	Ti6Al4V
59	213-7150-0000	4049852017039	Pectus Bar Implant	length: 38,0 cm	CE1011	Ti6Al4V
60	213-7160-0000	4049852017046	Pectus Bar Implant	length: 40,5 cm	CE1011	Ti6Al4V
61	213-7170-0000	4049852017053	Pectus Bar Implant	length: 43,0 cm	CE1011	Ti6Al4V
62	213-7180-0000	4049852017060	Pectus Bar Implant	length: 45,5 cm	CE1011	Ti6Al4V
63	213-8010-0000	4049852017077	Pectus Bar stabilisator plate	long	CE1011	Ti6Al4V
64	213-8020-0000	4049852017084	Pectus Bar stabilisator plate	short	CE1011	Ti6Al4V
65	213-8030-0000	4049852017091	Pectus Bar stabilisator plate	fixed	CE1011	Ti6Al4V

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NO.	Medical Device - Implant Class IIb					
	REFERENCE NUMBER	GTIN CODE	DESCRIPTION	SIZE (TYPE)	TYPE OF CE MARK	MATERIAL
66	213-8040-0000	4049852139847	fixation screw for fixed stabilisator plate	–	CE1011	Ti6Al4V

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02.	Grouping of risk classes			14.09.2020
03.	Clarification in the text of the declaration and in the annex			06.11.2020
04	Correction of Declaration at the request of the auditor. Update certificate numbers			04.10.2021
05	Headquarters address changed			01.04.2022