

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 Trial and Instrument accessories of „Biotech Pectus Bar Correct System”	
Document ID:	Version:	Document releasing date:	Page Number/ Number of Page(s):
DoC-CE-PE-D-CL-IIa-DCL	v06	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):

Trial and Instrument accessories for “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:

Trial and Instrument accessories for:

Biotech Pectus Bar Correct System

Trial and instrument Article Numbers:

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

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

Declaration:

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

UMDNS code:

16-349; 18-303

Classification:

Class II.a

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

Rheinbrohl, 01.04.2022

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Dr. Alkaysi Ghazi
General Director
Biotech GmbH

Company stamp

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Accessories – Instrument Article Numbers /Class II.a/ – Biotech Pectus Bar Correct System

NO.	Medical Device - INSTRUMENT Class II.a						NAME AND ID (REF. NO) OF INSTRUMENT SET
	REFERENCE NUMBER	GTIN CODE	DESCRIPTION	SIZE (TYPE)	TYPE OF CE MARK	MATERIAL	
1	113-8180-0000	4049852147743	Pectus Template, 45,5 cm	45,5 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
2	113-8170-0000	4049852147750	Pectus Template, 43,0 cm	43,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
3	113-8160-0000	4049852147767	Pectus Template, 40,5 cm	40,5 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
4	113-8150-0000	4049852147774	Pectus Template, 38,0 cm	38,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
5	113-8140-0000	4049852147781	Pectus Template, 35,5 cm	35,5 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
6	113-8130-0000	4049852147798	Pectus Template, 33,0 cm	33,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
7	113-8120-0000	4049852147804	Pectus Template, 30,5 cm	30,5 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000

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NO.	Medical Device - INSTRUMENT Class II.a						NAME AND ID (REF. NO) OF INSTRUMENT SET
	REFERENCE NUMBER	GTIN CODE	DESCRIPTION	SIZE (TYPE)	TYPE OF CE MARK	MATERIAL	
8	113-8110-0000	4049852147811	Pectus Template, 28,0 cm	28,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
9	113-8100-0000	4049852147828	Pectus Template, 25,5 cm	25,5 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
10	113-8090-0000	4049852147835	Pectus Template, 23,0 cm	23,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
11	113-8080-0000	4049852147842	Pectus Template, 20,5 cm	20,5 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
12	113-8070-0000	4049852147859	Pectus Template, 18,0 cm	18,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
13	113-8260-0000	4049852000949	Pectus Template, 17,0 cm	17,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
14	113-8250-0000	4049852001007	Pectus Template, 16,5 cm	16,5 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
15	113-8240-0000	4049852001014	Pectus Template, 16,0 cm	16,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000

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	REFERENCE NUMBER	GTIN CODE	DESCRIPTION	SIZE (TYPE)	TYPE OF CE MARK	MATERIAL	
16	113-8230-0000	4049852001021	Pectus Template, 15,5 cm	15,5 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
17	113-8220-0000	4049852001038	Pectus Template, 15,0 cm	15,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
18	113-8210-0000	4049852001045	Pectus Template, 14,5 cm	14,5 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
19	113-8000-0000	4049852001205	Pectus Template, 14,0 cm	14,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
20	113-7990-0000	4049852001212	Pectus Template, 13,5 cm	13,5 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
21	113-7980-0000	4049852006002	Pectus Template, 13,0 cm	13,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
22	113-7970-0000	4049852006484	Pectus Template, 12,5 cm	12,5 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
23	113-7960-0000	4049852006491	Pectus Template, 12,0 cm	12,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000

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	REFERENCE NUMBER	GTIN CODE	DESCRIPTION	SIZE (TYPE)	TYPE OF CE MARK	MATERIAL	
24	113-7950-0000	4049852006507	Pectus Template, 11,5 cm	11,5 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
25	113-7940-0000	4049852006514	Pectus Template, 11,0 cm	11,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
26	113-7930-0000	4049852006828	Pectus Template, 10,5 cm	10,5 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
27	113-7920-0000	4049852006989	Pectus Template, 10,0 cm	10,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
28	113-7900-0000	4049852006996	Pectus Template, 9,0 cm	9,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
29	113-7880-0000	4049852007009	Pectus Template, 8,0 cm	8,0 cm	II.a	Al	Biotech Pectus Instrument Set 113-9200-0000
30	113-9050-0000	4049852147866	Pectus Bender	-	II.a	W.Nr.1.4122	Biotech Pectus Instrument Set 113-9200-0000
31	113-9000-0000	4049852147873	Pectus Flipper	-	II.a	W.Nr.1.4122	Biotech Pectus Instrument Set 113-9200-0000

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	REFERENCE NUMBER	GTIN CODE	DESCRIPTION	SIZE (TYPE)	TYPE OF CE MARK	MATERIAL	
32	113-9090-0000	4049852147880	Pectus Introducer Small 48,0 cm	48,0 cm	II.a	W.Nr.1.4571	Biotech Pectus Instrument Set 113-9200-0000
33	113-9080-0000	4049852147897	Pectus Introducer Medium 51,0 cm	51,0 cm	II.a	W.Nr.1.4571	Biotech Pectus Instrument Set 113-9200-0000
34	113-9070-0000	4049852147903	Pectus Introducer Large 53,0 cm	53,0 cm	II.a	W.Nr.1.4571	Biotech Pectus Instrument Set 113-9200-0000
35	113-9060-0000	4049852186353	Screwdriver 2,5 mm	2,5 mm	II.a	W.Nr.1.4122, POM-C	Biotech Pectus Instrument Set 113-9200-0000
36	113-9040-0000	4049852147927	Pectus table bender	Pectus table bender	II.a	Al, W.Nr.1.4571, 1.4122	Biotech Pectus Instrument Set 113-9200-0000

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DOCUMENT INFORMATION				
DOCUMENT TITLE:				
EC – DECLARATION OF CONFORMITY FOR TRIAL AND INSTRUMENT ACCESSORIES OF „BIOTECH PECTUS BAR CORRECT SYSTEM”				
DOCUMENT				
ID:			TYPE:	
DoC-CE-PE-D-CL-IIa-CP		Release (version) number: 6		Declaration
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RESPONSIBILITIES				
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MADE BY:	Lackner Brigitta	Quality Systems Manager deputy Biotech GmbH Magyarországi Fióktelepe		01.04.2022
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EXPENDITURE/ AMENDMENT SERIAL NUMBER:	CHANGE / CHANGE DESCRIPTION:			RELEASE DATE:
01.	Development of a new document identification system and format, reviewing the adequacy of product data.			25.03.2020
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 reference number			01.03.2021
05	Marking of Class I. Correction of Declaration at the request of the auditor. Update certificate numbers			04.10.2021
06	Headquarters address changed			01.04.2022