	<b>Technical Construction File</b>	File No.	LBT-TCF-001-07
		Rev. No.	1
	<b>7. EU Declaration of Conformity</b>	Rev. Date	2022.04.13
		Page	1/6

## EU Declaration of Conformity

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device that is covered by the present declaration is in conformity with regulation (EU) 2017/745 and ISO 13485:2016. This declaration is issued under the sole responsibility of Libertech Corporation.

### Manufacturer

Name : Libertech Corporation  
Address : 1352, Poseungjangan-ro, Jangan-myeon, Hwaseong-si, Gyeonggi-do, Republic of Korea  
Single Registration Number : KR-MF-000024126

### Authorized Representative

Name : JaviTech e.K.  
Address : Sachsenhausener Straße 16, 65824 Schwalbach am Taunus, Germany  
Single Registration Number : DE-AR-000005875

### Device

Product Name : Operating room gel positioning pad  
Brand Name : Libertech operating room gel positioning pad  
Model : 187 models (Refer to Annex II. Model information)  
The Basic UDI-DI : 880923879LBT001LM


Intended Use : The device is intended to reduce pain and prevent pressure sore during medical operation.  
Risk Class : Class I according to Annex VIII of the regulation (EU) 2017/745  
Applied standards : Refer to Annex I Applied standards  
Conformity assessment route : Annex IV of Regulation (EU) 2017/745

Applied Common Specifications : No Common Specifications were applied.

April 13, 2022



CEO of Libertech Corporation

	<b>Technical Construction File</b>	File No.	LBT-TCF-001-07
		Rev. No.	1
	<b>7. EU Declaration of Conformity</b>	Rev. Date	2022.04.13
		Page	2/6

Annex I. Applied standards

No.	Name	Application
1	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
2	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
3	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
4	EN ISO 13485:2016	Medical devices - Quality management systems - requirements for regulatory purposes (ISO 13485: 2016)
5	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
6	ISO 10993-10:2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

**7. EU Declaration of Conformity**

## Annex II. model information

No.	Model name	Ref. No.
1	CLOSED HEAD RING	AP001
2		AP002
3		AP003
4		AP004
5	HAND/WRIST SUPPORT	AP005
6	OPEN HEAD RING	AP011
7		AP012
8		AP013
9		AP014
10	OPEN HEAD RING WITH CUT	AP011/C
11		AP012/C
12		AP013/C
13		AP014/C
14	FACE PAD	AP021
15	PRONE HEAD REST	AP022
16		AP023
17		AP024
18		HEIGHT ADJUSTABLE PRONE HEAD REST WITH MIRROR
19		AP026
20	HEEL SUPPORT PAD	AP031
21	HEEL CUPS without STRAPS	AP032
22	COMFORT HEEL CUPS with STRAP	AP033
23		AP034
24	CHEST ROLLS(ADULT)	AP041
25		AP042
26		AP043
27		AP044
28		AP045
29		AP046
30		AP047
31	CHEST ROLLS WHIT FLAT BOTTOM	AP047-1
32		AP047-2
33		AP047-3
34		AP047-4
35	CHEST ROLLS(PEDIATRIC)	AP048-1
36		AP048-2
37		AP048-3
38		AP048-4
39	CONTOURED CHEST ROLLS	AP049-1
40		AP049-2
41		AP049-3
42	CHEST POSITIONING SET	AP050-1
43		AP050-2
44	DOME POSITIONER	AP051
45	GRADUATED THORACIC POSITIONER	AP052
46		AP053
47	FRACTURE TABLE PAD	AP054
48	FRACTURE TABLE HIP PAD	AP055
49		AP056
50	WILSON FRAME PAD SET	AP212
51		AP213



Technical Construction File

File No.	LBT-TCF-001-07
Rev. No.	1
Rev. Date	2022.04.13
Page	4/6

7. EU Declaration of Conformity

52	WILSON FRAME PAD SET	AP214
53		AP215
54	ARM PROTECTOR	AP310
55		AP311
56	ARM BOARD PAD WITH FOAM	AP073
57		AP074
58		AP075
59		AP076
60	CONTOURED AMBOARD PAD	AP077
61	OPERATING TABLE PAD	AP301
62		AP302
63		AP303
64		AP303-1.5
65		AP304
66		AP304-1.5
67		AP305
68		AP306
69		AP307
70		AP308
71		AP308-1.5
72		AP401
73		AP402
74		AP402-1.5
75		AP403
76		AP403-1.5
77		AP404
78		AP053
79		AP405-1.5
80		AP406-1.5
81		AP407-1.5
82		AP408-1.5
83		AP412
84		AP412-1
85	AP410W/C	
86	AP410W/C-1.5	
87	AP411W/C	
88	AP411W/C-1.5	
89	AP409W/C	
90	AP409W/C-1.5	
91	3PCS OPERATING TABLE PAD	AP304
92		AP410W/C
93		AP411W/C
94	OPERATING ROOM GEL PAD	AP413
95		AP414
96		AP415
97		AP416
98		AP417
99		AP418
100		AP423
101		AP424
102		AP555
103		FRACTURE TABLE POST PAD
104	EMBOSSSED OPERATING TABLE PAD	AP061
105		AP062
106		AP063

7. EU Declaration of Conformity

107		AP064
108	PATIENT POSITIONING BELT	AP601
109	VAC-PAC COVER	AP701
110		AP801
111	CRUTCH STIRRUP PAD	AP802
112		AP803
113		AP804
114	BOOT STIRRUP PADS	AP901
115	TRACTION BOOT PAD COVER	AP902
116	LITHOTOMY POLE COVERS	AP903
117		AP904
118	ANKLE STRAP STIRRUPS	AP905
119		FB-01
120	GEL FASTENING STRAP	FB-02
121		AP102-3
122	SLANTING SHAPED PAD	AP102-6
123	SACRAL PROTECTOR	AP103-1
124		AP104-1
125	THYROID PAD	AP104-2
126	HEAD PAD	AP110
127	SUPINE HEADREST	AP112
128	SUPINE HEADREST	AP113
129	CONTOURED HEADREST	AP081
130		AP071
131	ARM BOARD PAD	AP072
132		AP091
133		AP092
134		AP093
135	UNIVERSAL PATIENT POSITIONER	AP094
136		AP095
137		AP097
138		AP097
139	LATERAL POSITIONER – UPPER BODY	AP101
140	LATERAL POSITIONER – LOWER BODY	AP103
141	ANGIO CATHETER TABLE	AP105
142	RELTON FRAME PAD SET	AP111
143		AP210
144	WILSON FRAME PAD	AP211
145		AP419
146	OPERATING TABLE PADWITH FOAM	AP420
147		AP421
148		AP422
149		AP002-UFG
150	CLOSED HEAD RING	AP003-UFG
151		AP004-UFG
152		AP012-UFG
153		AP013-UFG
154	OPEN HEADRING	AP014-UFG
155		AP012/C-UFG
156		AP013/C-UFG
157		AP022-UFG
158	PRONE HEAD REST	AP023-UFG
159	HEAD PAD	AP110-UFG
160	SUPINE HEADREST	AP112-UFG
161	CONTOURED HEADREST	AP081-UFG

162	CONTOURED AMBOARDPAD	AP077-UFG
163	HEEL SUPPORT PAD	AP031-UFG
164		AP032-UFG
165	HEEL SUPPORT CUSHION	AP035-UFG
166	CHEST ROLLS (ADULT)	AP041-UFG
167		AP042-UFG
168		AP043-UFG
169		AP044-UFG
170		AP045-UFG
171		AP046-UFG
172		CHEST ROLLS WITH FLATBOTTOM
173	AP047-2-UFG	
174	AP047-3-UFG	
175	AP047-4-UFG	
176	CHEST ROLLS (PEDIATRIC)	AP048-1-UFG
177		AP048-2-UFG
178		AP048-3-UFG
179		AP048-4-UFG
180	CONTOURED CHEST ROLLS	AP049-1-UFG
181		AP049-2-UFG
182		AP049-3-UFG
183		AP049-4-UFG
184		AP049-5-UFG
185	DOME POSITIONER	AP051-UFG
186	SLANTING SHAPED PAD	AP102-3-UFG
187		AP102-6-UFG