

Declaration of Conformity

Doc ID: ANT/CE-PCT-07



Manufacturer:

SHENZHEN ANTMED CO.,LTD.

18 Jinhui Ave., Pingshan New District, 518122 Shenzhen, CHINA

SRN of the manufacturer:

CN-MF-000029659

Medical Device:

Pressure Connecting Tube

Model:

5cm, 10cm, 15cm, 20cm, 25cm, 30cm, 40cm, 50cm, 60cm, 75cm, 80cm, 90cm, 100cm, 110cm, 120cm, 130cm, 150cm, 180cm, 200cm, 250cm, 300cm

REF

Please see annex I.

Basic UDI-DI:

69457644PCT0000002G2

Classification - Annex IX:

Class Is, Rule 2

Conformity assessment Route:

Annex IX of MDR on (EU) 2017/745

We, the manufacturer, here with declare on our own responsibility that the medical device: meet all the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical device, which apply to it. Every article we sell is covered by a technical documentation. Technical documentation are provided to the European Authorized Representative and kept up to date by us. We, the manufacturer, is exclusively responsible for the declaration of conformity.

Applied Standard

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 80369-7:2021, EN ISO 10993-1:2020, EN ISO 10993-4:2017, EN ISO 10993-5:2009, EN ISO 10993-7:2009, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-23:2021, EN ISO 10993-17:2023, EN ISO 10993-18:2020/A1:2023, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, EN ISO 11134:2014/A1:2019, EN 62366-1:2015/A1:2020, EN ISO 11607-1:2020/A1:2023, EN ISO 11607-2:2020/A1:2023, ASTM F 1980-21, ASTM D 4169-23e1, EN ISO 15223-1: 2021.

Notified Body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, Germany

Identification Number:

CE 0123

(EC) Certificate(s):

G11 004593 0012 Rev. 00

Exp. Date:

2029-02-05



MedNet EC-Rep C IIb GmbH
Borkstrasse 10, 48163 Muenster, Germany

SRN of the EC-REP:

DE-AR-000011194

Start of CE-marking:

2024-02-06

Place, Date of Declaration:

Shenzhen, 2025-10-29

Legally binding Signature:

Name: XIA GU

POSITION: Person Responsible for Regulatory Conformity (PRRC)

Declaration of Conformity

Annex I REF List

SN	REF	SN	REF	SN	REF	SN	REF
1	600101	39	650106	77	800102	115	HBR025
2	600102	40	650107	78	800103	116	HBR030
3	600103	41	650108	79	800104	117	HBR040
4	600104	42	650109	80	800105	118	HBR050
5	600105	43	650110	81	800106	119	HBR060
6	600106	44	650111	82	800107	120	HBR075
7	600107	45	650112	83	800108	121	HBR080
8	600108	46	650115	84	PTMF02	122	HBR090
9	600109	47	650116	85	PTMF03	123	HBR100
10	600112	48	650117	86	PTMF04	124	HBR120
11	600113	49	650118	87	PTMF06	125	HBR130
12	600122	50	650119	88	PTMF08	126	HBR150
13	600133	51	680301	89	PTMF09	127	HBR180
14	600134	52	680302	90	PTMF10	128	HBR200
15	600135	53	680303	91	PTMF11	129	HBR250
16	600137	54	680304	92	PTMF12	130	HBU150
17	600150	55	680305	93	PTMF13	131	HBU200
18	600151	56	680306	94	PTMF14		
19	600155	57	700201	95	PTMF16		
20	600158	58	700202	96	PTMF17		
21	601150	59	700203	97	PTMF18		
22	601155	60	700204	98	PTMF19		
23	602101	61	700205	99	PTMF51		
24	602151	62	700206	100	PTMF59		
25	602251	63	700208	101	PTMF60		
26	611005	64	700207	102	PTMF61		
27	611007	65	700209	103	PTMF62		
28	611009	66	700211	104	PTMM05		
29	611015	67	700212	105	PTMM06		
30	612801	68	700213	106	PTMM08		
31	612825	69	700214	107	PTMM12		
32	630050	70	700215	108	PTMM16		
33	640001	71	700216	109	PTMM19		
34	640002	72	700217	110	PTMM59		
35	640005	73	700218	111	HBR005		
36	650101	74	700219	112	HBR010		
37	650102	75	700220	113	HBR015		
38	650105	76	800101	114	HBR020		