

EU DECLARATION OF CONFORMITY

Document No. : DOC-001-05

Rev: B1

Manufacturer: Orantech Inc.

Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community, GongMing, Guangming
New District, Shenzhen, China.518106

SRN : CN-MF-000013859

EC- Representative: Medten EU ApS

Hejreskovvej 8, 3490 Kvistgård, Denmark

SRN : DK-AR-000034434

Product Name : Patient Cable (Air hose)

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH04QV

UMDNS Code : 16316

Classification - Annex VIII : Class I, Rule 1

Conformity Assessment Route : Annex IX

We, Orantech Inc., herewith declare that this EU declaration of conformity is issued under the sole responsibility of the manufacturer. The products mentioned above are in conformity with the Medical Device Regulation 2017/745. All supporting documentations are retained under the premises of the manufacturer. We, the manufacturer, are exclusively responsible for doc.

Standard Applied :

EN ISO13485: 2016

EN 1041:2008+A1:2013

EN ISO 14971:2019

EN ISO 15223-1: 2016

DIRECTIVE 2011/65/EU

Notified Body : TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany

CE mark : 

Valid Date From : 2020-01-10

Valid Date Until : 2024-05-26

Place, Date of Issue :

Signature : 

Shenzhen, Feb.26th, 2024

Position: General Manager

Annex I List of Air hose

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
BPH-AS25-02M-02M	06941691901778	BPH-NS30-39-06	06941691958345	BPH-NS25-02M-06	06941691901969
BPH-AS25-07-02M	06941691901785	BPH-NS30-01M-45	06941691959380	BPH-NS25-01M-06	06941691901976
BPH-AS25-01M-02M	06941691901792	BPH-NS30-01M-D45	06941691959397	BPH-NS25-07-06	06941691901983
BPH-AS25-02M-10	06941691901808	BPH-NS35-02M-06	06941691959977	BPH-NS25-03M-06	06941691901990
BPH-AS25-03M-04M	06941691901815	BPH-AD25-09M-09M	06941691902034	BPH-NS25-09M-06	06941691902003
BPH-AS25-03M-09M	06941691901822	BPH-AD25-13-09M	06941691902041	BPH-NS25-18-06	06941691902010
BPH-AS25-03M-02M	06941691901839	BPH-AD25-13-10	06941691902058	BPH-NS25-19-06	06941691902027
BPH-AS25-04M-02M	06941691901846	BPH-AD25-13-1011	06941691902065	BPH-NS25-07-35	06941691947394
BPH-AS25-09M-09M	06941691901853	BPH-AD25-14A-09M	06941691902072	BPH-NS35-03M-06	06941691958215
BPH-AS25-09M-10	06941691901860	BPH-AD25-14A-10	06941691902089	BPH-NS30-07-06	06941691958178
BPH-AS25-09M-11	06941691901877	BPH-AD25-14A-1011	06941691902096	BPH-ND36-13-17	06941691958154
BPH-AS25-09M-25	06941691901884	BPH-AD25-16-09M	06941691902102	BPH-TS-29-02M	06941691902416
BPH-AS25-10-11	06941691901891	BPH-AD25-16-10	06941691902119	BPH-TS-29-06	06941691902423
BPH-AS25-18-02M	06941691901907	BPH-AD25-15A-S11	06941691902126	BPH-ND25-09M-17	06941691902317
BPH-AS37-18-02M	06941691901914	BPH-AD25-23-S11	06941691902133	BPH-ND25-13-17	06941691902324
BPH-AS25-19-20	06941691901921	BPH-AD25-24-09M	06941691902140	BPH-ND25-14N-17	06941691902331
BPH-AS25-21-2TM	06941691901938	BPH-AD25-24-10	06941691902157	BPH-ND25-16-17	06941691902348
BPH-AS03-08-25	06941691901945	BPH-AD25-24-11	06941691902164	BPH-ND25-15N-S06	06941691902355
BPH-AS25-09M-N	06941691901952	BPH-AD25-24-26	06941691902171	BPH-ND25-23-S06	06941691902362
BPH-AS25-39-10	06941691947356	BPH-AD36-09M-09M	06941691902188	BPH-ND30-13-17	06941691902379
BPH-AS25-39-02M	06941691947363	BPH-AD36-13-09M	06941691902195	BPH-ND36-16-17	06941691902386
BPH-AS25-07-25	06941691947370	BPH-AD36-13-10	06941691902201	BPH-ND35-15N-S06	06941691902393
BPH-AS36-07-02M	06941691947387	BPH-AD36-13-1011	06941691902218	BPH-ND35-23-S06	06941691902409
BPH-AS07-01M-25	06941691954125	BPH-AD36-14A-09M	06941691902225	BPH-ND36-14N-17	06941691947462
BPH-AS25-07-35	06941691954644	BPH-AD36-14A-10	06941691902232	BPH-ND25-14N-33	06941691947479
BPH-AS30-39-25	06941691955153	BPH-AD36-14A-1011	06941691902249	BPH-ND36-16-33	06941691958116
BPH-AS37-18-43	06941691957973	BPH-AD36-16-09M	06941691902256	BPH-AD36-16-32	06941691947455
BPH-AS25-42-10	06941691958000	BPH-AD36-16-10	06941691902263	BPH-AD03-14A-32	06941691958048
BPH-AS30-12-12	06941691958147	BPH-AD15-15A-S11	06941691902270	BPH-AD25-09M-10	06941691958185
BPH-AS15-02M-04M	06941691958192	BPH-AD15-23-S11	06941691902287	BPH-AD30-24-10	06941691958314

BPH-AS30-07-02M	06941691958222	BPH-AD35-15A-S11	06941691902294	BPH-AD30-24-26	06941691958321
BPH-AS30-02M-02M	06941691958246	BPH-AD35-23-S11	06941691902300	BPH-AD30-24-09M	06941691959090
BPH-AS30-01M-02M	06941691958260	BPH-AD36-14A-32	06941691947400	BPH-AD73-16-09M	06941691959182
BPH-AS30-09M-09M	06941691958277	BPH-AD72-14A-32	06941691947417	BPH-AD25-24-N	06941691960058
BPH-AS30-09M-10	06941691958284	BPH-AD12-14A-32	06941691947424	BPH-AD35-24-26	06941691960553
BPH-AS30-09M-25	06941691958291	BPH-AD25-14A-26	06941691947431	BPH-AD30-13-1011	06941691962045
BPH-AS30-39-10	06941691958338	BPH-AD36-14A-26	06941691947448	BPH-AD50-14A-10	06941691962991
BPH-AS30-02M-10	06941691958352	BPH-AS30-21-02M	06941691959908	BPC12	06941691973782
BPH-AS25-21-02M	06941691958765	BPH-AS10-01M-02M	06941691959922	BPC48	06941691973799
BPH-AS18-09M-10	06941691959007	BPH-AS35-02M-02M	06941691959984	BPH-AS30-07Z-02M	06941691963059
BPH-AS75-07-02M	06941691959212	BPH-AS35-03M-02M	06941691960546	BPA-Y-10-NN	06941691973867
BPH-AS25-08-25	06941691959588	BPH-AS60-07-02M	06941691962663	BPA-S-01M-25	06941691973706
BPH-AS25-12-02M	06941691959595	BPH-AS25-19-02M	06941691901921	BPA-D-1111-26	06941691973546
BPH-NS30-07Z-06	06941691973751	BPHB-ND36-16-33	06941691971429	BPHB-ND36-16-17	06941691971405
BPHB-ND25-14N-33	06941691971412	BPHB-ND25-14N-17	06941691971399	BPTA-Y-G001-2TP02M	06941691971443
BPTA-S(80)-54-25	06941691973508	BPTA-S(61)-54-25	06941691972990	BPTA-D-N-54(33)-26	06941691971450
BPTA-D-N(33)-54-26	06941691971481	BPTA-D-G001-54-26	06941691972938	BPTA-D-G001-2TP-26	06941691973515
BPTA-D-G001-1010	06941691971436	BPTA-D(80)-N-54-26	06941691971474	BPTA-D(61)-N-54-26	06941691971467
BPH-AS30-07Z-02M	06941691963059	BPH-AS25-07Z-02M	06941691963448	BPC38	06941694875229
BPC10	06941694675201	BPC11	06941694775215	BPTA-Y-G004-2TP02M	06941691974796
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BPTA-D-G004-09M	06941691975199	BPTA-D-G003-54-26	06941691974765	BPTA-D-G003-2TP-26	06941691974802
BPTA-D-G002-54-26	06941691974611	BPTA-D-G001W-54-26	06941691974628	BPTA-D006-3838-1011	06941691974703
BPH-NS30-39-40	06941691974116	BPH-NS30-059Z-60	06941691975151	BPH-NS15-059Z-60	06941691975144
BPH-AS30-07Z-25	06941691974260	BPH-AS30-07-25	06941691974109	BPH-AS30-059Z-02M	06941691975175
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BPH-AS12-01M-02M	06941691975519	BPH-AD30-58-S11	06941691974352	BPH-AD30-57-10	06941691974192
BPA-Y-05P-4040	06941691974130	BPA-Y-02M-05P05P	06941691974697	BPA-Y-01M-32	06941691974673
BPA-Y-01M-09M09M	06941691974680	BPA-S-43-11	06941691974376	BPA-S-43-10	06941691974369
BPA-S-2TP-25	06941691974819	BPA-S-25-11	06941691974208	BPA-S-11-43	06941691974888
BPA-S-11-25	06941691974833	BPA-S-10-43	06941691974871	BPA-S-08-25	06941691974826
BPA-S-05P-40	06941691974123	BPA-S-01P-25	06941691974215	BPA-D-2TP2TP-26	06941691974840
BPA-D-26-1111	06941691974222	BPA-D-26-1011	06941691974239	BPA-D-1011-32	06941691975342

BPA-D-1011-26	06941691974864	BPA-D-0808-26	06941691974857	BPH-AS15-39-10	06941691971733
BPH-AD15-26-N	06941691971740	BPH-AD30-26-N	06941691971757	BPH-AD15-24-1010	06941691971764
BPH-ND36-14N-S06	06941691971771	BPA-Y-N-1011	06941691971788	BPA-Y-N-1010	06941691971795
BPA-Y-N-09M09M	06941691971801	BPA-Y-N-2TP2TP	06941691971818	BPA-Y-N-0606	06941691971825
BPA-Y-01M-NN	06941691971832	BPA-Y-01M-1011	06941691971849	BPA-Y-01M-1010	06941691971856
BPA-Y-01M-2TP2TP	06941691971863	BPA-Y-01M-0606	06941691971870	BPA-Y-11-NN	06941691971887
BPA-Y-11-1011	06941691971894	BPA-Y-11-1010	06941691971900	BPA-Y-11-09M09M	06941691971917
BPA-Y-11-2TP2TP	06941691971924	BPA-Y-11-0606	06941691971931	BPA-Y-03M-NN	06941691971948
BPA-Y-03M-1011	06941691971955	BPA-Y-03M-1010	06941691971962	BPA-Y-03M-09M09M	06941691971979
BPA-Y-03M-2TP2TP	06941691971986	BPA-Y-03M-0606	06941691971993	BPA-Y-08-NN	06941691972006
BPA-Y-08-1011	06941691972013	BPA-Y-08-1010	06941691972020	BPA-Y-08-09M09M	06941691972037
BPA-Y-08-2TP2TP	06941691972044	BPA-Y-08-0606	06941691972051	BPA-Y-2TP-NN	06941691972068
BPA-Y-2TP-1011	06941691972075	BPA-Y-2TP-1010	06941691972082	BPA-Y-2TP-09M09M	06941691972099
BPA-Y-2TP-2TP2TP	06941691972105	BPA-Y-2TP-0606	06941691972112	BPA-Y-12-NN	06941691972129
BPA-Y-12-1011	06941691972136	BPA-Y-12-1010	06941691972143	BPA-Y-12-09M09M	06941691972150
BPA-Y-12-2TP2TP	06941691972167	BPA-Y-12-0606	06941691972174	BPA-Y-N-2TM2TM	06941691972181
BPA-Y-N-32	06941691972198	BPA-Y-01M-2TM2TM	06941691972204	BPA-Y-03M-2TM2TM	06941691972211
BPA-Y-03M-32	06941691972228	BPA-Y-04M-1010	06941691972235	BPA-Y-04M-1011	06941691972242
BPA-Y-04M-09M09M	06941691972259	BPA-Y-04M-2TM2TM	06941691972266	BPA-Y-04M-32	06941691972273
BPA-Y-10-1010	06941691972280	BPA-Y-10-1011	06941691972297	BPA-Y-10-09M09M	06941691972303
BPA-Y-10-2TM2TM	06941691972310	BPA-Y-10-32	06941691972327	BPA-Y-11-2TM2TM	06941691972334
BPA-Y-11-32	06941691972341	BPA-Y-37-1010	06941691972358	BPA-Y-37-1011	06941691972365
BPA-Y-37-09M09M	06941691972372	BPA-Y-37-2TM2TM	06941691972389	BPA-Y-37-32	06941691972396
BPA-Y-05M-17	06941691972402	BPA-Y-05M-33	06941691972419	BPA-Y-05M-4545	06941691972426
BPA-Y-36-17	06941691972433	BPA-Y-36-33	06941691972440	BPA-Y-36-4545	06941691972457
BPA-Y-3TY-0808	06941691972464	BPA-Y-3TY-1111	06941691972471	BPA-Y-3TY-38	06941691972488
BPA-Y-02M-3TY	06941691972495	BPA-Y-02M-0808	06941691972501	BPA-Y-02M-1011	06941691972518
BPA-Y-02M-1111	06941691972525	BPA-Y-02M-38	06941691972532	BPA-Y-04M-3TY	06941691972549
BPA-Y-04M-0808	06941691972556	BPA-Y-04M-1111	06941691972563	BPA-Y-04M-38	06941691972570
BPA-Y-09M-3TY	06941691972587	BPA-Y-09M-0808	06941691972594	BPA-Y-09M-1011	06941691972600
BPA-Y-09M-1111	06941691972617	BPA-Y-09M-38	06941691972624	BPA-Y-10-N	06941691972631
BPA-Y-10-0808	06941691972648	BPA-Y-10-1111	06941691972655	BPA-Y-10-38	06941691972662
BPA-Y-11-0808	06941691972679	BPA-Y-11-1111	06941691972686	BPA-Y-11-38	06941691972693
BPA-Y-25-3TY	06941691972709	BPA-Y-25-0808	06941691972716	BPA-Y-25-1011	06941691972723

BPA-Y-25-1111	06941691972730	BPA-Y-25-38	06941691972747	BPA-Y-43-3TY	06941691972754
BPA-Y-43-0808	06941691972761	BPA-Y-43-1011	06941691972778	BPA-Y-43-1111	06941691972785
BPA-Y-43-38	06941691972792	BPA-Y-06-N	06941691972808	BPA-Y-06-05M05M	06941691972815
BPA-Y-06-3434	06941691972822	BPA-Y-36-N	06941691972839	BPA-Y-35-05M05M	06941691972846
BPA-Y-35-3434	06941691972853	BPA-Y-01M-02M02M	06941691972860	BPA-S-25-01P	06941691972877
BPA-S-25-10	06941691972884	BPA-Y-01P-1010	06941691972891	BPA-D-26-2TP2TP	06941691972907
BPA-D-26-0808	06941691972914	BPA-D-09M09M-2TP2TP	06941691972921	BPTA-T-02M-01M02M	06941691972945
BPTA-T-02M-1011	06941691972952	BPTA-T-02M-03M05M	06941691972969	BPTA-T-02M-0809M	06941691972976
BPTA-T-B-3TP	06941691972983	BPC02M	06941691972495	BPC10-D	06941691978954
BS17	06941691978947	BPA-Y-01M-03M03M	06941691977513	BPC24	06941691978671
BPC25	06941691978688	BPC26	06941691978695	BPC28	06941691978701
BPC37	06941691978664	BPC39	06941691978718	BPC42	06941691978725
BPHB-ND35-15N-S06	06941691978787	BISA-MR01-30	06941691959120	BISA-AP01-30	06941691959137
BISA-GE01-30	06941691964988	BISA-3F01-30	06941691973492	BISA-PH01-30	06941691966869
BISA-SY01-30	06941691974031	BISA-SLG01-30	06941691974253	BISA-FD01-30	06941691975649
BISB-AP01-13	06941691964971	BISB-AP02-13	06941691966081		