

## ***EU DECLARATION OF CONFORMITY***

**Document No. :** DOC-001-05

**Rev:** A3

**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:** Cables and Sensors B.V.

Zekeringstraat 21B , 1014 BM Amsterdam, Netherlands

SRN : NL-AR-000012545

**Product Name :** Patient Cable ( Air hose )

**Product Models :** Please see the Annex I

**Basic UDI - DI:** 69416919ORANTECH04QV

**UMDNS Code :** 16316

**Classification(MDR Annex VIII) :** Class I, Rule1

**Conformity Assessment Route :** Annex II +III in 2017/745/EEC MDR

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, the provisions of council MDR 2017/745/EEC of 26 May, 2020 concerning medical devices. All supporting documentations are retained under the premises of the manufacturer. We, the manufacturer, are exclusively responsible for doc.

**Standard Applied :**

EN ISO 14971:2019

EN ISO 15223-1:2020

EN ISO 10993-1:2018

EN ISO 10993-5:2009

EN ISO 10993-10:2010

ISO 81060-1:2012

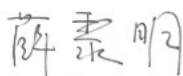
**Notified Body :** TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany

**CE mark :** 

**Valid Date From :** 2020-01-10

**Valid Date Until :** 2024-05-26

**Place, Date of Issue :**

**Signature :** 

Shenzhen, July. 1<sup>st</sup>, 2021

**Position:** General Manager

**Orantech Inc.**

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### Annex I List of Air hose

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
BPH-AS25-02M-02M	6941691901778	BPH-NS30-39-06	6941691958345	BPH-NS25-02M-06	6941691901969
BPH-AS25-07-02M	6941691901785	BPH-NS30-01M-45	6941691959380	BPH-NS25-01M-06	6941691901976
BPH-AS25-01M-02M	6941691901792	BPH-NS30-01M-D45	6941691959397	BPH-NS25-07-06	6941691901983
BPH-AS25-02M-10	6941691901808	BPH-NS35-02M-06	6941691959977	BPH-NS25-03M-06	6941691901990
BPH-AS25-03M-04M	6941691901815	BPH-AD25-09M-09M	6941691902034	BPH-NS25-09M-06	6941691902003
BPH-AS25-03M-09M	6941691901822	BPH-AD25-13-09M	6941691902041	BPH-NS25-18-06	6941691902010
BPH-AS25-03M-02M	6941691901839	BPH-AD25-13-10	6941691902058	BPH-NS25-19-06	6941691902027
BPH-AS25-04M-02M	6941691901846	BPH-AD25-13-1011	6941691902065	BPH-NS25-07-35	6941691947394
BPH-AS25-09M-09M	6941691901853	BPH-AD25-14A-09M	6941691902072	BPH-NS35-03M-06	6941691958215
BPH-AS25-09M-10	6941691901860	BPH-AD25-14A-10	6941691902089	BPH-NS30-07-06	6941691958178
BPH-AS25-09M-11	6941691901877	BPH-AD25-14A-1011	6941691902096	BPH-ND36-13-17	6941691958154
BPH-AS25-09M-25	6941691901884	BPH-AD25-16-09M	6941691902102	BPH-TS-29-02M	6941691902416
BPH-AS25-10-11	6941691901891	BPH-AD25-16-10	6941691902119	BPH-TS-29-06	6941691902423
BPH-AS25-18-02M	6941691901907	BPH-AD25-15A-S11	6941691902126	BPH-ND25-09M-17	6941691902317
BPH-AS37-18-02M	6941691901914	BPH-AD25-23-S11	6941691902133	BPH-ND25-13-17	6941691902324
BPH-AS25-19-20	6941691901921	BPH-AD25-24-09M	6941691902140	BPH-ND25-14N-17	6941691902331
BPH-AS25-21-2TM	6941691901938	BPH-AD25-24-10	6941691902157	BPH-ND25-16-17	6941691902348
BPH-AS03-08-25	6941691901945	BPH-AD25-24-11	6941691902164	BPH-ND25-15N-S06	6941691902355
BPH-AS25-09M-N	6941691901952	BPH-AD25-24-26	6941691902171	BPH-ND25-23-S06	6941691902362
BPH-AS25-39-10	6941691947356	BPH-AD36-09M-09M	6941691902188	BPH-ND30-13-17	6941691902379
BPH-AS25-39-02M	6941691947363	BPH-AD36-13-09M	6941691902195	BPH-ND36-16-17	6941691902386
BPH-AS25-07-25	6941691947370	BPH-AD36-13-10	6941691902201	BPH-ND35-15N-S06	6941691902393
BPH-AS36-07-02M	6941691947387	BPH-AD36-13-1011	6941691902218	BPH-ND35-23-S06	6941691902409
BPH-AS07-01M-25	6941691954125	BPH-AD36-14A-09M	6941691902225	BPH-ND36-14N-17	6941691947462
BPH-AS25-07-35	6941691954644	BPH-AD36-14A-10	6941691902232	BPH-ND25-14N-33	6941691947479
BPH-AS30-39-25	6941691955153	BPH-AD36-14A-1011	6941691902249	BPH-ND36-16-33	6941691958116
BPH-AS37-18-43	6941691957973	BPH-AD36-16-09M	6941691902256	BPH-AD36-16-32	6941691947455
BPH-AS25-42-10	6941691958000	BPH-AD36-16-10	6941691902263	BPH-AD03-14A-32	6941691958048
BPH-AS30-12-12	6941691958147	BPH-AD15-15A-S11	6941691902270	BPH-AD25-09M-10	6941691958185
BPH-AS15-02M-04M	6941691958192	BPH-AD15-23-S11	6941691902287	BPH-AD30-24-10	6941691958314
BPH-AS30-07-02M	6941691958222	BPH-AD35-15A-S11	6941691902294	BPH-AD30-24-26	6941691958321

BPH-AS30-02M-02M	6941691958246	BPH-AD35-23-S11	6941691902300	BPH-AD30-24-09M	6941691959090
BPH-AS30-01M-02M	6941691958260	BPH-AD36-14A-32	6941691947400	BPH-AD73-16-09M	6941691959182
BPH-AS30-09M-09M	6941691958277	BPH-AD72-14A-32	6941691947417	BPH-AD25-24-N	6941691960058
BPH-AS30-09M-10	6941691958284	BPH-AD12-14A-32	6941691947424	BPH-AD35-24-26	6941691960553
BPH-AS30-09M-25	6941691958291	BPH-AD25-14A-26	6941691947431	BPH-AD30-13-1011	6941691962045
BPH-AS30-39-10	6941691958338	BPH-AD36-14A-26	6941691947448	BPH-AD50-14A-10	6941691962991
BPH-AS30-02M-10	6941691958352	BPH-AS30-21-02M	6941691959908		
BPH-AS25-21-02M	6941691958765	BPH-AS10-01M-02M	6941691959922		
BPH-AS18-09M-10	6941691959007	BPH-AS35-02M-02M	6941691959984		
BPH-AS75-07-02M	6941691959212	BPH-AS35-03M-02M	6941691960546		
BPH-AS25-08-25	6941691959588	BPH-AS60-07-02M	6941691962663		
BPH-AS25-12-02M	6941691959595	BPH-AS25-19-02M	6941691901921		