

EU DECLARATION OF CONFORMITY

Document No. : DOC-001-03

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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

Oldenvej 33, 3490 Kvistgård, Denmark
SRN : DK-AR-000034434

Product Name : Patient Cables (IBP Adapter Cables)

Product Models : Please see the Annex I

Basic UDI -DI: 69416919ORANTECH03QT

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: 2021

Directive 2011/65/EU Annex II (EU) 2015/863

Notified Body : TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany

CE mark : 

Place, Date of Issue :

Shenzhen, Feb.17th, 2025

Signature : 

Position: General Manager

Annex I List of IBP Adapter Cables

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
IBP-DG-2EW40	06941691981411	IBP-ME-USBAM30	06970706364970	IBP-GT-EW40	06970706362860
IBP-FDC-EW40	06941691980865	IBP-KR-USBAM30	06970706364963	IBP-IG-EW40	06970706362853
IBPA-SM-SM07	06941691964919	IBP-SR-USBAM30	06970706364956	IBP-CM-EW40	06970706362846
IBPC-AG-MXT03	06941691980506	IBP-SK-USBAM30	06970706364949	IBP-BR-EW40	06970706362839
IBPC-AG-BB03	06941691980513	IBP-LT-USBAM30	06970706364932	IBP-ME-EW40	06970706362822
IBP-3PH-3EW40	06941691979616	IBP-ET-USBAM30	06970706364925	IBP-KR-EW40	06970706362815
IBP-AM02-MXT40	06941691977179	IBP-FDB-USBAM30	06970706364918	IBP-SR-EW40	06970706362808
IBP-AM02-EW40	06941691977186	IBP-FDA-USBAM30	06970706364901	IBP-SK-EW40	06970706362792
IBPC-BD-UT03	06941691971290	IBP-MN-USBAM30	06970706364895	IBP-LT-EW40	06970706362785
IBPC-MXT-UT03	06941691971283	IBP-INF-USBAM30	06970706364888	IBP-ET-EW40	06970706362778
IBPC-EW-UT03	06941691971276	IBP-CSI-USBAM30	06970706364871	IBP-FDB-EW40	06970706362761
IBPC-MXT-BD03	06941691971269	IBP-HL-USBAM30	06970706364864	IBP-FDA-EW40	06970706362754
IBP-PH-MD015	06941691971252	IBP-MEK-USBAM30	06970706364857	IBP-MN-EW40	06970706362747
IBP-NKA-MD015	06941691971245	IBP-CL-USBAM30	06970706364840	IBP-INF-EW40	06970706362730
IBP-AM-MD015	06941691971238	IBP-KTN-USBAM30	06970706364833	IBP-CSI-EW40	06970706362723
IBP-MQ-MD015	06941691971221	IBP-BLT-USBAM30	06970706364826	IBP-HL-EW40	06970706362716
IBP-FDA-MD015	06941691971214	IBP-DT-USBAM30	06970706364819	IBP-MEK-EW40	06970706362709
IBP-DGA-MD015	06941691971207	IBP-CR-USBAM30	06970706364802	IBP-CL-EW40	06970706362693
IBP-DX-MD015	06941691971191	IBP-MRB-USBAM30	06970706364796	IBP-KTN-EW40	06970706362686

IBP-DT-MD015	06941691971184	IBP-MRA-USBAM30	06970706364789	IBP-BLT-EW40	06970706362679
IBP-BR-USBAM15	06941691971177	IBP-DGE-USBAM30	06970706364772	IBP-DT-EW40	06970706362662
IBP-CSI-USBAM15	06941691971160	IBP-DGD-USBAM30	06970706364765	IBP-CR-EW40	06970706362655
IBP-PH-USBAM15	06941691971153	IBP-DGC-USBAM30	06970706364758	IBP-MRB-EW40	06970706362648
IBP-NKA-USBAM15	06941691971146	IBP-DGB-USBAM30	06970706364741	IBP-MRA-EW40	06970706362631
IBP-AM-USBAM15	06941691971139	IBP-DGA-USBAM30	06970706364734	IBP-DGE-EW40	06970706362624
IBP-MQ-USBAM15	06941691971122	IBP-NKC-USBAM30	06970706364727	IBP-DGD-EW40	06970706362617
IBP-FDA-USBAM15	06941691971115	IBP-NKB-USBAM30	06970706364710	IBP-DGC-EW40	06970706362600
IBP-DGA-USBAM15	06941691971108	IBP-NKA-USBAM30	06970706364703	IBP-DGB-EW40	06970706362594
IBP-DX-USBAM15	06941691971092	IBP-SL-USBAM30	06970706364697	IBP-DGA-EW40	06970706362587
IBP-DT-USBAM15	06941691971085	IBP-DX-USBAM30	06970706364680	IBP-NKC-EW40	06970706362570
IBP-CA-MXT40	06941691971078	IBP-GE-USBAM30	06970706364673	IBP-NKB-EW40	06970706362563
IBP-CA-BD40	06941691967187	IBP-MQ-USBAM30	06970706364666	IBP-NKA-EW40	06970706362556
IBP-DGA-MT05	06941691968306	IBP-PH-USBAM30	06970706364659	IBP-SL-EW40	06970706362549
IBPC-EW-MXT03	06941691966975	IBP-AM-USBAM30	06970706364642	IBP-DX-EW40	06970706362532
IBPC-BB-UT03	06941691966968	IBP-HY-AG40	06970706364635	IBP-GE-EW40	06970706362525
IBPC-EW-BB03	06941691966951	IBP-JJB-AG40	06970706364628	IBP-MQ-EW40	06970706362518
IBP-PH01-UT04	06941691965770	IBP-JJA-AG40	06970706364611	IBP-PH-EW40	06970706362501
IBP-AM01-USBAM30	06941691965473	IBP-FS-AG40	06970706364604	IBP-AM-EW40	06970706362495
IBP-AM01-AG40	06941691965466	IBP-SA-AG40	06970706364598	IBP-HY-BB40	06970706362488
IBP-AM01-MIR40	06941691965459	IBP-GT-AG40	06970706364581	IBP-JJB-BB40	06970706362471
IBP-AM01-PVB40	06941691965442	IBP-IG-AG40	06970706364574	IBP-JJA-BB40	06970706362464

IBP-AM01-BD40	06941691965435	IBP-CM-AG40	06970706364567	IBP-FS-BB40	06970706362457
IBP-AM01-EW40	06941691965428	IBP-BR-AG40	06970706364550	IBP-SA-BB40	06970706362440
IBP-AM01-BB40	06941691965411	IBP-ME-AG40	06970706364543	IBP-GT-BB40	06970706362433
IBP-AM01-UT40	06941691965404	IBP-KR-AG40	06970706364536	IBP-IG-BB40	06970706362426
IBP-AM01-MXL40	06941691965398	IBP-SR-AG40	06970706364529	IBP-CM-BB40	06970706362419
IBP-AM01-MXT40	06941691965381	IBP-SK-AG40	06970706364512	IBP-BR-BB40	06970706362402
IBPC-MXT-EW03	06941691965015	IBP-LT-AG40	06970706364505	IBP-ME-BB40	06970706362396
IBP-PH01-BD04	06941691963080	IBP-ET-AG40	06970706364499	IBP-KR-BB40	06970706362389
IBP-PH-EW60	06941691962700	IBP-FDB-AG40	06970706364482	IBP-SR-BB40	06970706362372
IBP-MD-UT40	06941691961741	IBP-FDA-AG40	06970706364475	IBP-SK-BB40	06970706362365
IBP-FDC-UT40	06941691961734	IBP-MN-AG40	06970706364468	IBP-LT-BB40	06970706362358
IBP-PH01-MXT04	06941691962823	IBP-INF-AG40	06970706364451	IBP-ET-BB40	06970706362341
IBPA-PH-2PH04	06941691963431	IBP-CSI-AG40	06970706364444	IBP-FDB-BB40	06970706362334
IBPA-MRA-2AM03	06941691958703	IBP-HL-AG40	06970706364437	IBP-FDA-BB40	06970706362327
IBP-PH01-EW04	06941691958079	IBP-MEK-AG40	06970706364420	IBP-MN-BB40	06970706362310
IBP-PH01-PVB04	06941691958062	IBP-CL-AG40	06970706364413	IBP-INF-BB40	06970706362303
IBP-PH01-MXL04	06941691958055	IBP-KTN-AG40	06970706364406	IBP-CSI-BB40	06970706362297
IBP-FDC-MXL40	06941691957904	IBP-BLT-AG40	06970706364390	IBP-HL-BB40	06970706362280
IBPC-EW-BD03	06941691954866	IBP-DT-AG40	06970706364383	IBP-MEK-BB40	06970706362273
IBPC-BD-EW03	06941691947158	IBP-CR-AG40	06970706364376	IBP-CL-BB40	06970706362266
IBPC-BB-EW03	06941691947141	IBP-MRB-AG40	06970706364369	IBP-KTN-BB40	06970706362259
IBPC-UT-EW03	06941691947134	IBP-MRA-AG40	06970706364352	IBP-BLT-BB40	06970706362242

IBPC-BD-BB03	06941691947127	IBP-DGE-AG40	06970706364345	IBP-DT-BB40	06970706362235
IBPC-ED-BB03	06941691947110	IBP-DGD-AG40	06970706364338	IBP-CR-BB40	06970706362228
IBPC-MXT-BB03	06941691947103	IBP-DGC-AG40	06970706364321	IBP-MRB-BB40	06970706362211
IBPC-UT-BB03	06941691947097	IBP-DGB-AG40	06970706364314	IBP-MRA-BB40	06970706362204
IBP-3MQ-3EW40	06941691907145	IBP-DGA-AG40	06970706364307	IBP-DGE-BB40	06970706362198
IBP-MRA-2MD40	06941691906858	IBP-NKC-AG40	06970706364291	IBP-DGD-BB40	06970706362181
IBP-DGC-2MD40	06941691906827	IBP-NKB-AG40	06970706364284	IBP-DGC-BB40	06970706362174
IBP-DGC-2USBAM40	06941691906391	IBP-NKA-AG40	06970706364277	IBP-DGB-BB40	06970706362167
IBP-MRA-2AG40	06941691905998	IBP-SL-AG40	06970706364260	IBP-DGA-BB40	06970706362150
IBP-DGC-2AG40	06941691905967	IBP-DX-AG40	06970706364253	IBP-NKC-BB40	06970706362143
IBP-PH-2AG40	06941691905868	IBP-GE-AG40	06970706364246	IBP-NKB-BB40	06970706362136
IBP-MRA-2MIR40	06941691905561	IBP-MQ-AG40	06970706364239	IBP-NKA-BB40	06970706362129
IBP-DGC-2MIR40	06941691905530	IBP-PH-AG40	06970706364222	IBP-SL-BB40	06970706362112
IBP-PH-2MIR40	06941691905431	IBP-AM-AG40	06970706364215	IBP-DX-BB40	06970706362105
IBP-MRA-2PVB40	06941691905134	IBP-HY-MIR40	06970706364208	IBP-GE-BB40	06970706362099
IBP-DGC-2PVB40	06941691905103	IBP-JJB-MIR40	06970706364192	IBP-MQ-BB40	06970706362082
IBP-PH-2PVB40	06941691905004	IBP-JJA-MIR40	06970706364185	IBP-PH-BB40	06970706362075
IBP-MRA-2BD40	06941691904700	IBP-FS-MIR40	06970706364178	IBP-AM-BB40	06970706362068
IBP-DGC-2BD40	06941691904670	IBP-SA-MIR40	06970706364161	IBP-HY-UT40	06970706362051
IBP-MQ-2BD40	06941691904588	IBP-GT-MIR40	06970706364154	IBP-JJB-UT40	06970706362044
IBP-PH-2BD40	06941691904571	IBP-IG-MIR40	06970706364147	IBP-JJA-UT40	06970706362037
IBP-MRA-2EW40	06941691904274	IBP-CM-MIR40	06970706364130	IBP-FS-UT40	06970706362020

IBP-DGC-2EW40	06941691904243	IBP-BR-MIR40	06970706364123	IBP-SA-UT40	06970706362013
IBP-MQ-2EW40	06941691904151	IBP-ME-MIR40	06970706364116	IBP-GT-UT40	06970706362006
IBP-PH-2EW40	06941691904144	IBP-KR-MIR40	06970706364109	IBP-IG-UT40	06970706361993
IBP-MRA-2BB40	06941691903840	IBP-SR-MIR40	06970706364093	IBP-CM-UT40	06970706361986
IBP-DGC-2BB40	06941691903819	IBP-SK-MIR40	06970706364086	IBP-BR-UT40	06970706361979
IBP-SL-2BB40	06941691903758	IBP-LT-MIR40	06970706364079	IBP-ME-UT40	06970706361962
IBP-PH-2BB40	06941691903710	IBP-ET-MIR40	06970706364062	IBP-KR-UT40	06970706361955
IBP-MRA-2UT40	06941691903413	IBP-FDB-MIR40	06970706364055	IBP-SR-UT40	06970706361948
IBP-DGC-2UT40	06941691903383	IBP-FDA-MIR40	06970706364048	IBP-SK-UT40	06970706361931
IBP-MQ-2UT40	06941691903291	IBP-MN-MIR40	06970706364031	IBP-LT-UT40	06970706361924
IBP-PH-2UT40	06941691903284	IBP-INF-MIR40	06970706364024	IBP-ET-UT40	06970706361917
IBP-MRA-2MXL40	06941691902980	IBP-CSI-MIR40	06970706364017	IBP-FDB-UT40	06970706361900
IBP-DGC-2MXL40	06941691902959	IBP-HL-MIR40	06970706364000	IBP-FDA-UT40	06970706361894
IBP-PH-2MXL40	06941691902850	IBP-MEK-MIR40	06970706363997	IBP-MN-UT40	06970706361887
IBPC-BB-BD03	06970706366493	IBP-CL-MIR40	06970706363980	IBP-INF-UT40	06970706361870
IBPC-UT-BD03	06970706366486	IBP-KTN-MIR40	06970706363973	IBP-CSI-UT40	06970706361863
IBPC-BD-MXT03	06970706366479	IBP-BLT-MIR40	06970706363966	IBP-HL-UT40	06970706361856
IBPC-ED-MXT03	06970706366462	IBP-DT-MIR40	06970706363959	IBP-MEK-UT40	06970706361849
IBPC-BB-MXT03	06970706366455	IBP-CR-MIR40	06970706363942	IBP-CL-UT40	06970706361832
IBPC-UT-MXT03	06970706366448	IBP-MRB-MIR40	06970706363935	IBP-KTN-UT40	06970706361825
IBPA-DG-2DGB03	06970706366431	IBP-MRA-MIR40	06970706363928	IBP-BLT-UT40	06970706361818
IBPA-DG-2DGA03	06970706366424	IBP-DGE-MIR40	06970706363911	IBP-DT-UT40	06970706361801

IBPA-DGB-2DGA03	06970706366417	IBP-DGD-MIR40	06970706363904	IBP-CR-UT40	06970706361795
IBPA-DGA-2DGB03	06970706366400	IBP-DGC-MIR40	06970706363898	IBP-MRB-UT40	06970706361788
IBPA-SL-2AM03	06970706366394	IBP-DGB-MIR40	06970706363881	IBP-MRA-UT40	06970706361771
IBPA-MQ-2MQ03	06970706366387	IBP-DGA-MIR40	06970706363874	IBP-DGE-UT40	06970706361764
IBPA-MQ-2AM03	06970706366370	IBP-NKC-MIR40	06970706363867	IBP-DGD-UT40	06970706361757
IBPA-DGB-DGA03	06970706366363	IBP-NKB-MIR40	06970706363850	IBP-DGC-UT40	06970706361740
IBPA-DGA-DGB03	06970706366356	IBP-NKA-MIR40	06970706363843	IBP-DGB-UT40	06970706361733
IBPA-HY-AM03	06970706366349	IBP-SL-MIR40	06970706363836	IBP-DGA-UT40	06970706361726
IBPA-JJB-AM03	06970706366332	IBP-DX-MIR40	06970706363829	IBP-NKC-UT40	06970706361719
IBPA-JJA-AM03	06970706366325	IBP-GE-MIR40	06970706363812	IBP-NKB-UT40	06970706361702
IBPA-FS-AM03	06970706366318	IBP-MQ-MIR40	06970706363805	IBP-NKA-UT40	06970706361696
IBPA-SA-AM03	06970706366301	IBP-PH-MIR40	06970706363799	IBP-SL-UT40	06970706361689
IBPA-GT-AM03	06970706366295	IBP-AM-MIR40	06970706363782	IBP-DX-UT40	06970706361672
IBPA-IG-AM03	06970706366288	IBP-HY-PVB40	06970706363775	IBP-GE-UT40	06970706361665
IBPA-CM-AM03	06970706366271	IBP-JJB-PVB40	06970706363768	IBP-MQ-UT40	06970706361658
IBPA-BR-AM03	06970706366264	IBP-JJA-PVB40	06970706363751	IBP-PH-UT40	06970706361641
IBPA-ME-AM03	06970706366257	IBP-FS-PVB40	06970706363744	IBP-AM-UT40	06970706361634
IBPA-KR-AM03	06970706366240	IBP-SA-PVB40	06970706363737	IBP-HY-MXL40	06970706361627
IBPA-SR-AM03	06970706366233	IBP-GT-PVB40	06970706363720	IBP-JJB-MXL40	06970706361610
IBPA-SK-AM03	06970706366226	IBP-IG-PVB40	06970706363713	IBP-JJA-MXL40	06970706361603
IBPA-LT-AM03	06970706366219	IBP-CM-PVB40	06970706363706	IBP-FS-MXL40	06970706361597
IBPA-ET-AM03	06970706366202	IBP-BR-PVB40	06970706363690	IBP-SA-MXL40	06970706361580

IBPA-FDB-AM03	06970706366196	IBP-ME-PVB40	06970706363683	IBP-GT-MXL40	06970706361573
IBPA-FDA-AM03	06970706366189	IBP-KR-PVB40	06970706363676	IBP-IG-MXL40	06970706361566
IBPA-MN-AM03	06970706366172	IBP-SR-PVB40	06970706363669	IBP-CM-MXL40	06970706361559
IBPA-INF-AM03	06970706366165	IBP-SK-PVB40	06970706363652	IBP-BR-MXL40	06970706361542
IBPA-CSI-AM03	06970706366158	IBP-LT-PVB40	06970706363645	IBP-ME-MXL40	06970706361535
IBPA-HL-AM03	06970706366141	IBP-ET-PVB40	06970706363638	IBP-KR-MXL40	06970706361528
IBPA-MEK-AM03	06970706366134	IBP-FDB-PVB40	06970706363621	IBP-SR-MXL40	06970706361511
IBPA-CL-AM03	06970706366127	IBP-FDA-PVB40	06970706363614	IBP-SK-MXL40	06970706361504
IBPA-KTN-AM03	06970706366110	IBP-MN-PVB40	06970706363607	IBP-LT-MXL40	06970706361498
IBPA-BLT-AM03	06970706366103	IBP-INF-PVB40	06970706363591	IBP-ET-MXL40	06970706361481
IBPA-DT-AM03	06970706366097	IBP-CSI-PVB40	06970706363584	IBP-FDB-MXL40	06970706361474
IBPA-CR-AM03	06970706366080	IBP-HL-PVB40	06970706363577	IBP-FDA-MXL40	06970706361467
IBPA-MRB-AM03	06970706366073	IBP-MEK-PVB40	06970706363560	IBP-MN-MXL40	06970706361450
IBPA-MRA-AM03	06970706366066	IBP-CL-PVB40	06970706363553	IBP-INF-MXL40	06970706361443
IBPA-DGE-AM03	06970706366059	IBP-KTN-PVB40	06970706363546	IBP-CSI-MXL40	06970706361436
IBPA-DGD-AM03	06970706366042	IBP-BLT-PVB40	06970706363539	IBP-HL-MXL40	06970706361429
IBPA-DGC-AM03	06970706366035	IBP-DT-PVB40	06970706363522	IBP-MEK-MXL40	06970706361412
IBPA-DGB-AM03	06970706366028	IBP-CR-PVB40	06970706363515	IBP-CL-MXL40	06970706361405
IBPA-DGA-AM03	06970706366011	IBP-MRB-PVB40	06970706363508	IBP-KTN-MXL40	06970706361399
IBPA-NKC-AM03	06970706366004	IBP-MRA-PVB40	06970706363492	IBP-BLT-MXL40	06970706361382
IBPA-NKB-AM03	06970706365991	IBP-DGE-PVB40	06970706363485	IBP-DT-MXL40	06970706361375
IBPA-NKA-AM03	06970706365984	IBP-DGD-PVB40	06970706363478	IBP-CR-MXL40	06970706361368

IBPA-SL-AM03	06970706365977	IBP-DGC-PVB40	06970706363461	IBP-MRB-MXL40	06970706361351
IBPA-DX-AM03	06970706365960	IBP-DGB-PVB40	06970706363454	IBP-MRA-MXL40	06970706361344
IBPA-GE-AM03	06970706365953	IBP-DGA-PVB40	06970706363447	IBP-DGE-MXL40	06970706361337
IBPA-MQ-AM03	06970706365946	IBP-NKC-PVB40	06970706363430	IBP-DGD-MXL40	06970706361320
IBPA-PH-AM03	06970706365939	IBP-NKB-PVB40	06970706363423	IBP-DGC-MXL40	06970706361313
IBP-MRA-2MXT40	06970706365649	IBP-NKA-PVB40	06970706363416	IBP-DGB-MXL40	06970706361306
IBP-DGC-2MXT40	06970706365618	IBP-SL-PVB40	06970706363409	IBP-DGA-MXL40	06970706361290
IBP-PH-2MXT40	06970706365519	IBP-DX-PVB40	06970706363393	IBP-NKC-MXL40	06970706361283
IBP-HY-MD03	06970706365496	IBP-GE-PVB40	06970706363386	IBP-NKB-MXL40	06970706361276
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