

EU DECLARATION OF CONFORMITY

Document No. : DOC-001-03

Rev: B3

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

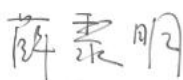
Directive 2011/65/EU Annex II (EU) 2015/863

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

CE mark : 

Place, Date of Issue :

Shenzhen, Aug.27th, 2024

Signature : 

Position: General Manager

Annex I List of IBP Adapter Cables

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
IBP-AM-MXT40	06970706360767	IBPC-UT-EW03	06941691947134	IBPC-BB-EW03	06941691947141
IBP-PH-MXT40	06970706360774	IBPC-EW-BD03	06941691954866	IBP-FDC-EW40	06941691980865
IBP-MQ-MXT40	06970706360781	IBP-BR-EW40	06970706362839	IBPA-CSI-AM03	06970706366158
IBP-GE-MXT40	06970706360798	IBP-CM-EW40	06970706362846	IBPA-INF-AM03	06970706366165
IBP-DX-MXT40	06970706360804	IBP-IG-EW40	06970706362853	IBPA-MN-AM03	06970706366172
IBP-SL-MXT40	06970706360811	IBP-GT-EW40	06970706362860	IBPA-FDA-AM03	06970706366189
IBP-NKA-MXT40	06970706360828	IBP-SA-EW40	06970706362877	IBPA-FDB-AM03	06970706366196
IBP-NKB-MXT40	06970706360835	IBP-FS-EW40	06970706362884	IBPA-ET-AM03	06970706366202
IBP-NKC-MXT40	06970706360842	IBP-JJA-EW40	06970706362891	IBPA-LT-AM03	06970706366219
IBP-DGA-MXT40	06970706360859	IBP-JJB-EW40	06970706362907	IBPA-SK-AM03	06970706366226
IBP-DGB-MXT40	06970706360866	IBP-HY-EW40	06970706362914	IBPA-SR-AM03	06970706366233
IBP-DGC-MXT40	06970706360873	IBP-PH01-EW04	06941691958079	IBPA-KR-AM03	06970706366240
IBP-DGD-MXT40	06970706360880	IBP-PH-EW60	06941691962700	IBPA-ME-AM03	06970706366257
IBP-DGE-MXT40	06970706360897	IBP-AM-BD40	06970706362921	IBPA-BR-AM03	06970706366264
IBP-MRA-MXT40	06970706360903	IBP-PH-BD40	06970706362938	IBPA-CM-AM03	06970706366271
IBP-MRB-MXT40	06970706360910	IBP-MQ-BD40	06970706362945	IBPA-IG-AM03	06970706366288
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IBP-BLT-MXT40	06970706360941	IBP-SL-BD40	06970706362976	IBPA-FS-AM03	06970706366318
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IBP-CL-MXT40	06970706360965	IBP-NKB-BD40	06970706362990	IBPA-JJB-AM03	06970706366332
IBP-MEK-MXT40	06970706360972	IBP-NKC-BD40	06970706363003	IBPA-HY-AM03	06970706366349
IBP-HL-MXT40	06970706360989	IBP-DGA-BD40	06970706363010	IBPA-PH-AM03	06970706365939
IBP-CSI-MXT40	06970706360996	IBP-DGB-BD40	06970706363027	IBPA-MQ-AM03	06970706365946
IBP-INF-MXT40	06970706361009	IBP-DGC-BD40	06970706363034	IBPA-GE-AM03	06970706365953
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IBP-LT-MXT40	06970706361054	IBP-CR-BD40	06970706363089	IBPA-NKC-AM03	06970706366004
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IBP-SR-MXT40	06970706361078	IBP-BLT-BD40	06970706363102	IBPA-DGB-AM03	06970706366028
IBP-KR-MXT40	06970706361085	IBP-KTN-BD40	06970706363119	IBPA-DGC-AM03	06970706366035
IBP-ME-MXT40	06970706361092	IBP-CL-BD40	06970706363126	IBPA-DGD-AM03	06970706366042
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IBP-CM-MXT40	06970706361115	IBP-HL-BD40	06970706363140	IBPA-MRA-AM03	06970706366066
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IBP-GT-MXT40	06970706361139	IBP-INF-BD40	06970706363164	IBPA-CR-AM03	06970706366080
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IBP-JJA-MXT40	06970706361160	IBP-FDB-BD40	06970706363195	IBPA-KTN-AM03	06970706366110
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IBP-HY-MXT40	06970706361184	IBP-LT-BD40	06970706363218	IBPA-MEK-AM03	06970706366134
IBP-MD-MXT06	06970706361191	IBP-SK-BD40	06970706363225	IBPA-HL-AM03	06970706366141
IBP-PH01-MXT04	06941691962823	IBP-SR-BD40	06970706363232	IBPA-MQ-2AM03	06970706366370
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IBP-PH-MXL40	06970706361214	IBP-ME-BD40	06970706363256	IBP-PH-USBAM30	06970706364659
IBP-MQ-MXL40	06970706361221	IBP-BR-BD40	06970706363263	IBP-MQ-USBAM30	06970706364666
IBP-GE-MXL40	06970706361238	IBP-CM-BD40	06970706363270	IBP-GE-USBAM30	06970706364673
IBP-DX-MXL40	06970706361245	IBP-IG-BD40	06970706363287	IBP-DX-USBAM30	06970706364680
IBP-SL-MXL40	06970706361252	IBP-GT-BD40	06970706363294	IBP-SL-USBAM30	06970706364697
IBP-NKA-MXL40	06970706361269	IBP-SA-BD40	06970706363300	IBP-NKA-USBAM30	06970706364703
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IBP-DGA-MXL40	06970706361290	IBP-JJB-BD40	06970706363331	IBP-DGA-USBAM30	06970706364734
IBP-DGB-MXL40	06970706361306	IBP-HY-BD40	06970706363348	IBP-DGB-USBAM30	06970706364741
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IBP-DGD-MXL40	06970706361320	IBP-PH-PVB40	06970706363362	IBP-DGD-USBAM30	06970706364765
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IBP-SR-MXL40	06970706361511	IBP-CL-PVB40	06970706363553	IBP-SR-USBAM30	06970706364956
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IBP-BR-MXL40	06970706361542	IBP-CSI-PVB40	06970706363584	IBP-BR-USBAM30	06970706364987
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IBP-SA-MXL40	06970706361580	IBP-FDB-PVB40	06970706363621	IBP-SA-USBAM30	06970706365021

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IBP-JJB-MXL40	06970706361610	IBP-SK-PVB40	06970706363652	IBP-JJB-USBAM30	06970706365052
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IBP-MQ-UT40	06970706361658	IBP-IG-PVB40	06970706363713	IBP-MQ-MD03	06970706365090
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IBP-DX-UT40	06970706361672	IBP-SA-PVB40	06970706363737	IBP-DX-MD03	06970706365113
IBP-SL-UT40	06970706361689	IBP-FS-PVB40	06970706363744	IBP-SL-MD03	06970706365120
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IBP-NKC-UT40	06970706361719	IBP-HY-PVB40	06970706363775	IBP-NKC-MD03	06970706365151
IBP-DGA-UT40	06970706361726	IBP-PH01-PVB04	06941691958062	IBP-DGA-MD03	06970706365168
IBP-DGB-UT40	06970706361733	IBP-AM-MIR40	06970706363782	IBP-DGB-MD03	06970706365175
IBP-DGC-UT40	06970706361740	IBP-PH-MIR40	06970706363799	IBP-DGC-MD03	06970706365182
IBP-DGD-UT40	06970706361757	IBP-MQ-MIR40	06970706363805	IBP-DGD-MD03	06970706365199
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IBP-MRA-UT40	06970706361771	IBP-DX-MIR40	06970706363829	IBP-MRA-MD03	06970706365212
IBP-MRB-UT40	06970706361788	IBP-SL-MIR40	06970706363836	IBP-MRB-MD03	06970706365229

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IBP-DT-UT40	06970706361801	IBP-NKB-MIR40	06970706363850	IBP-DT-MD03	06970706365243
IBP-BLT-UT40	06970706361818	IBP-NKC-MIR40	06970706363867	IBP-BLT-MD03	06970706365250
IBP-KTN-UT40	06970706361825	IBP-DGA-MIR40	06970706363874	IBP-KTN-MD03	06970706365267
IBP-CL-UT40	06970706361832	IBP-DGB-MIR40	06970706363881	IBP-CL-MD03	06970706365274
IBP-MEK-UT40	06970706361849	IBP-DGC-MIR40	06970706363898	IBP-MEK-MD03	06970706365281
IBP-HL-UT40	06970706361856	IBP-DGD-MIR40	06970706363904	IBP-HL-MD03	06970706365298
IBP-CSI-UT40	06970706361863	IBP-DGE-MIR40	06970706363911	IBP-CSI-MD03	06970706365304
IBP-INF-UT40	06970706361870	IBP-MRA-MIR40	06970706363928	IBP-INF-MD03	06970706365311
IBP-MN-UT40	06970706361887	IBP-MRB-MIR40	06970706363935	IBP-FS-MD03	06970706365465
IBP-FDA-UT40	06970706361894	IBP-CR-MIR40	06970706363942	IBP-JJA-MD03	06970706365472
IBP-FDB-UT40	06970706361900	IBP-DT-MIR40	06970706363959	IBP-JJB-MD03	06970706365489
IBP-ET-UT40	06970706361917	IBP-BLT-MIR40	06970706363966	IBP-HY-MD03	06970706365496
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IBP-SK-UT40	06970706361931	IBP-CL-MIR40	06970706363980	IBP-FDA-MD03	06970706365335
IBP-SR-UT40	06970706361948	IBP-MEK-MIR40	06970706363997	IBP-FDB-MD03	06970706365342
IBP-KR-UT40	06970706361955	IBP-HL-MIR40	06970706364000	IBP-ET-MD03	06970706365359
IBP-ME-UT40	06970706361962	IBP-CSI-MIR40	06970706364017	IBP-LT-MD03	06970706365366
IBP-BR-UT40	06970706361979	IBP-INF-MIR40	06970706364024	IBP-SK-MD03	06970706365373
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IBP-IG-UT40	06970706361993	IBP-FDA-MIR40	06970706364048	IBP-KR-MD03	06970706365397
IBP-GT-UT40	06970706362006	IBP-FDB-MIR40	06970706364055	IBP-ME-MD03	06970706365403

IBP-SA-UT40	06970706362013	IBP-ET-MIR40	06970706364062	IBP-BR-MD03	06970706365410
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IBP-AM-BB40	06970706362068	IBP-ME-MIR40	06970706364116	IBP-AM-EW40	06970706362495
IBP-PH-BB40	06970706362075	IBP-BR-MIR40	06970706364123	IBP-PH-EW40	06970706362501
IBP-MQ-BB40	06970706362082	IBP-CM-MIR40	06970706364130	IBP-MQ-EW40	06970706362518
IBP-GE-BB40	06970706362099	IBP-IG-MIR40	06970706364147	IBP-GE-EW40	06970706362525
IBP-DX-BB40	06970706362105	IBP-GT-MIR40	06970706364154	IBP-DX-EW40	06970706362532
IBP-SL-BB40	06970706362112	IBP-SA-MIR40	06970706364161	IBP-SL-EW40	06970706362549
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IBP-NKB-BB40	06970706362136	IBP-JJA-MIR40	06970706364185	IBP-NKB-EW40	06970706362563
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IBP-DGA-BB40	06970706362150	IBP-HY-MIR40	06970706364208	IBP-DGA-EW40	06970706362587
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IBP-DGC-BB40	06970706362174	IBP-PH-AG40	06970706364222	IBP-DGC-EW40	06970706362600
IBP-DGD-BB40	06970706362181	IBP-MQ-AG40	06970706364239	IBP-DGD-EW40	06970706362617
IBP-DGE-BB40	06970706362198	IBP-GE-AG40	06970706364246	IBP-DGE-EW40	06970706362624
IBP-MRA-BB40	06970706362204	IBP-DX-AG40	06970706364253	IBP-MRA-EW40	06970706362631
IBP-MRB-BB40	06970706362211	IBP-SL-AG40	06970706364260	IBP-MRB-EW40	06970706362648
IBP-CR-BB40	06970706362228	IBP-NKA-AG40	06970706364277	IBP-CR-EW40	06970706362655

IBP-DT-BB40	06970706362235	IBP-NKB-AG40	06970706364284	IBP-DT-EW40	06970706362662
IBP-BLT-BB40	06970706362242	IBP-NKC-AG40	06970706364291	IBP-BLT-EW40	06970706362679
IBP-KTN-BB40	06970706362259	IBP-DGA-AG40	06970706364307	IBP-KTN-EW40	06970706362686
IBP-CL-BB40	06970706362266	IBP-DGB-AG40	06970706364314	IBP-CL-EW40	06970706362693
IBP-MEK-BB40	06970706362273	IBP-DGC-AG40	06970706364321	IBP-MEK-EW40	06970706362709
IBP-HL-BB40	06970706362280	IBP-DGD-AG40	06970706364338	IBP-HL-EW40	06970706362716
IBP-CSI-BB40	06970706362297	IBP-DGE-AG40	06970706364345	IBP-CSI-EW40	06970706362723
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IBP-MN-BB40	06970706362310	IBP-MRB-AG40	06970706364369	IBP-MN-EW40	06970706362747
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IBP-SK-BB40	06970706362365	IBP-CL-AG40	06970706364413	IBP-SK-EW40	06970706362792
IBP-SR-BB40	06970706362372	IBP-MEK-AG40	06970706364420	IBP-SR-EW40	06970706362808
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IBP-PH-2MXL40	06941691902850	IBP-HY-2MXT40	06970706365922	IBP-AM-2MXL40	06941691902843
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IBP-NKB-2MXL40	06941691902911	IBP-SL-2MXL40	06941691902898	IBP-NKA-2MXL40	06941691902904
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IBP-MN-2MXL40	06941691903093	IBP-CSI-2MXL40	06941691903079	IBP-INF-2MXL40	06941691903086
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IBP-SR-2MXL40	06941691903154	IBP-LT-2MXL40	06941691903130	IBP-SK-2MXL40	06941691903147
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IBP-GE-2UT40	06941691903307	IBP-PH-2UT40	06941691903284	IBP-MQ-2UT40	06941691903291
IBP-NKA-2UT40	06941691903338	IBP-DX-2UT40	06941691903314	IBP-SL-2UT40	06941691903321
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IBP-MEK-2UT40	06941691903482	IBP-KTN-2UT40	06941691903468	IBP-CL-2UT40	06941691903475
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IBP-KR-2PVB40	06941691905318	IBP-IG-2MD40	06941691907077	IBP-NKB-2MD40	06941691906780
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IBP-BR-2PVB40	06941691905332	IBP-SA-2MD40	06941691907091	IBP-DGA-2MD40	06941691906803
IBP-CM-2PVB40	06941691905349	IBP-FS-2MD40	06941691907107	IBP-DGB-2MD40	06941691906810

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IBP-JJB-2PVB40	06941691905400	IBP-MD-UT40	06941691961741	IBP-CR-2MD40	06941691906872
IBP-HY-2PVB40	06941691905417	IBP-PH01-BD04	06941691963080	IBP-DT-2MD40	06941691906889
IBP-AM-2MIR40	06941691905424	IBP-NKB-2USBAM40	06941691906353	IBP-BLT-2MD40	06941691906896
IBP-PH-2MIR40	06941691905431	IBP-NKC-2USBAM40	06941691906360	IBP-KTN-2MD40	06941691906902
IBP-MQ-2MIR40	06941691905448	IBP-DGA-2USBAM40	06941691906377	IBP-CL-2MD40	06941691906919
IBP-GE-2MIR40	06941691905455	IBP-DGB-2USBAM40	06941691906384	IBP-MEK-2MD40	06941691906926
IBP-DX-2MIR40	06941691905462	IBP-DGC-2USBAM40	06941691906391	IBP-HL-2MD40	06941691906933
IBP-SL-2MIR40	06941691905479	IBP-DGD-2USBAM40	06941691906407	IBP-CSI-2MD40	06941691906940
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IBP-NKB-2MIR40	06941691905493	IBP-MRA-2USBAM40	06941691906421	IBP-MN-2MD40	06941691906964
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IBP-MRA-2MIR40	06941691905561	IBP-MEK-2USBAM40	06941691906490	IBP-LT-2AG40	06941691906148

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IBP-DT-2MIR40	06941691905592	IBP-INF-2USBAM40	06941691906520	IBP-KR-2AG40	06941691906179
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IBPA-SM-SM07	06941691964919				