

EU DECLARATION OF CONFORMITY

Document No. : DOC-001-03

Rev: A7

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 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: 2016

DIRECTIVE 2011/65/EU

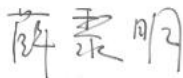
Notified Body : TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany

CE mark : 

Valid Date From : 2020-01-10

Valid Date Until : 2024-05-26

Place, Date of Issue :

Signature : 

Shenzhen, Apr.12th, 2024

Position: General Manager

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Annex I List of IBP Adapter Cables

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
IBP-AM-MXT40	06970706360767	IBP-BR-EW40	06970706362839	IBPA-CSI-AM03	06970706366158
IBP-PH-MXT40	06970706360774	IBP-CM-EW40	06970706362846	IBPA-INF-AM03	06970706366165
IBP-MQ-MXT40	06970706360781	IBP-IG-EW40	06970706362853	IBPA-MN-AM03	06970706366172
IBP-GE-MXT40	06970706360798	IBP-GT-EW40	06970706362860	IBPA-FDA-AM03	06970706366189
IBP-DX-MXT40	06970706360804	IBP-SA-EW40	06970706362877	IBPA-FDB-AM03	06970706366196
IBP-SL-MXT40	06970706360811	IBP-FS-EW40	06970706362884	IBPA-ET-AM03	06970706366202
IBP-NKA-MXT40	06970706360828	IBP-JJA-EW40	06970706362891	IBPA-LT-AM03	06970706366219
IBP-NKB-MXT40	06970706360835	IBP-JJB-EW40	06970706362907	IBPA-SK-AM03	06970706366226
IBP-NKC-MXT40	06970706360842	IBP-HY-EW40	06970706362914	IBPA-SR-AM03	06970706366233
IBP-DGA-MXT40	06970706360859	IBP-PH01-EW04	06941691958079	IBPA-KR-AM03	06970706366240
IBP-DGB-MXT40	06970706360866	IBP-PH-EW60	06941691962700	IBPA-ME-AM03	06970706366257
IBP-DGC-MXT40	06970706360873	IBP-AM-BD40	06970706362921	IBPA-BR-AM03	06970706366264
IBP-DGD-MXT40	06970706360880	IBP-PH-BD40	06970706362938	IBPA-CM-AM03	06970706366271
IBP-DGE-MXT40	06970706360897	IBP-MQ-BD40	06970706362945	IBPA-IG-AM03	06970706366288
IBP-MRA-MXT40	06970706360903	IBP-GE-BD40	06970706362952	IBPA-GT-AM03	06970706366295
IBP-MRB-MXT40	06970706360910	IBP-DX-BD40	06970706362969	IBPA-SA-AM03	06970706366301
IBP-CR-MXT40	06970706360927	IBP-SL-BD40	06970706362976	IBPA-FS-AM03	06970706366318
IBP-DT-MXT40	06970706360934	IBP-NKA-BD40	06970706362983	IBPA-JJA-AM03	06970706366325
IBP-BLT-MXT40	06970706360941	IBP-NKB-BD40	06970706362990	IBPA-JJB-AM03	06970706366332
IBP-KTN-MXT40	06970706360958	IBP-NKC-BD40	06970706363003	IBPA-HY-AM03	06970706366349
IBP-CL-MXT40	06970706360965	IBP-DGA-BD40	06970706363010	IBPA-PH-AM03	06970706365939
IBP-MEK-MXT40	06970706360972	IBP-DGB-BD40	06970706363027	IBPA-MQ-AM03	06970706365946
IBP-HL-MXT40	06970706360989	IBP-DGC-BD40	06970706363034	IBPA-GE-AM03	06970706365953
IBP-CSI-MXT40	06970706360996	IBP-DGD-BD40	06970706363041	IBPA-DX-AM03	06970706365960
IBP-INF-MXT40	06970706361009	IBP-DGE-BD40	06970706363058	IBPA-SL-AM03	06970706365977
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IBP-FDB-MXT40	06970706361030	IBP-CR-BD40	06970706363089	IBPA-NKC-AM03	06970706366004
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IBP-LT-MXT40	06970706361054	IBP-BLT-BD40	06970706363102	IBPA-DGB-AM03	06970706366028
IBP-SK-MXT40	06970706361061	IBP-KTN-BD40	06970706363119	IBPA-DGC-AM03	06970706366035
IBP-SR-MXT40	06970706361078	IBP-CL-BD40	06970706363126	IBPA-DGD-AM03	06970706366042
IBP-KR-MXT40	06970706361085	IBP-MEK-BD40	06970706363133	IBPA-DGE-AM03	06970706366059
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IBP-IG-MXT40	06970706361122	IBP-MN-BD40	06970706363171	IBPA-DT-AM03	06970706366097
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IBP-HY-MXT40	06970706361184	IBP-SR-BD40	06970706363232	IBPA-MQ-2AM03	06970706366370
IBP-MD-MXT06	06970706361191	IBP-KR-BD40	06970706363249	IBP-AM-USBAM30	06970706364642
IBP-PH01-MXT04	06941691962823	IBP-ME-BD40	06970706363256	IBP-PH-USBAM30	06970706364659
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IBP-PH-MXL40	06970706361214	IBP-CM-BD40	06970706363270	IBP-GE-USBAM30	06970706364673
IBP-MQ-MXL40	06970706361221	IBP-IG-BD40	06970706363287	IBP-DX-USBAM30	06970706364680
IBP-GE-MXL40	06970706361238	IBP-GT-BD40	06970706363294	IBP-SL-USBAM30	06970706364697
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IBP-NKC-MXL40	06970706361283	IBP-HY-BD40	06970706363348	IBP-DGB-USBAM30	06970706364741
IBP-DGA-MXL40	06970706361290	IBP-AM-PVB40	06970706363355	IBP-DGC-USBAM30	06970706364758
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IBP-CL-UT40	06970706361832	IBP-DGD-MIR40	06970706363904	IBP-HL-MD03	06970706365298
IBP-MEK-UT40	06970706361849	IBP-DGE-MIR40	06970706363911	IBP-CSI-MD03	06970706365304
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IBP-CSI-UT40	06970706361863	IBP-MRB-MIR40	06970706363935	IBP-FS-MD03	06970706365465
IBP-INF-UT40	06970706361870	IBP-CR-MIR40	06970706363942	IBP-JJA-MD03	06970706365472
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IBP-FDA-UT40	06970706361894	IBP-BLT-MIR40	06970706363966	IBP-HY-MD03	06970706365496
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IBP-LT-UT40	06970706361924	IBP-MEK-MIR40	06970706363997	IBP-FDB-MD03	06970706365342
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IBP-SR-UT40	06970706361948	IBP-CSI-MIR40	06970706364017	IBP-LT-MD03	06970706365366
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IBP-ME-UT40	06970706361962	IBP-MN-MIR40	06970706364031	IBP-SR-MD03	06970706365380
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IBP-CM-UT40	06970706361986	IBP-FDB-MIR40	06970706364055	IBP-ME-MD03	06970706365403
IBP-IG-UT40	06970706361993	IBP-ET-MIR40	06970706364062	IBP-BR-MD03	06970706365410
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IBP-MQ-BB40	06970706362082	IBP-GT-MIR40	06970706364154	IBP-DX-EW40	06970706362532
IBP-GE-BB40	06970706362099	IBP-SA-MIR40	06970706364161	IBP-SL-EW40	06970706362549
IBP-DX-BB40	06970706362105	IBP-FS-MIR40	06970706364178	IBP-NKA-EW40	06970706362556
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IBP-NKB-BB40	06970706362136	IBP-HY-MIR40	06970706364208	IBP-DGA-EW40	06970706362587
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IBP-DGA-BB40	06970706362150	IBP-PH-AG40	06970706364222	IBP-DGC-EW40	06970706362600
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IBP-DGC-BB40	06970706362174	IBP-GE-AG40	06970706364246	IBP-DGE-EW40	06970706362624
IBP-DGD-BB40	06970706362181	IBP-DX-AG40	06970706364253	IBP-MRA-EW40	06970706362631
IBP-DGE-BB40	06970706362198	IBP-SL-AG40	06970706364260	IBP-MRB-EW40	06970706362648
IBP-MRA-BB40	06970706362204	IBP-NKA-AG40	06970706364277	IBP-CR-EW40	06970706362655
IBP-MRB-BB40	06970706362211	IBP-NKB-AG40	06970706364284	IBP-DT-EW40	06970706362662
IBP-CR-BB40	06970706362228	IBP-NKC-AG40	06970706364291	IBP-BLT-EW40	06970706362679
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IBP-BLT-BB40	06970706362242	IBP-DGB-AG40	06970706364314	IBP-CL-EW40	06970706362693
IBP-KTN-BB40	06970706362259	IBP-DGC-AG40	06970706364321	IBP-MEK-EW40	06970706362709
IBP-CL-BB40	06970706362266	IBP-DGD-AG40	06970706364338	IBP-HL-EW40	06970706362716
IBP-MEK-BB40	06970706362273	IBP-DGE-AG40	06970706364345	IBP-CSI-EW40	06970706362723
IBP-HL-BB40	06970706362280	IBP-MRA-AG40	06970706364352	IBP-INF-EW40	06970706362730
IBP-CSI-BB40	06970706362297	IBP-MRB-AG40	06970706364369	IBP-MN-EW40	06970706362747
IBP-INF-BB40	06970706362303	IBP-CR-AG40	06970706364376	IBP-FDA-EW40	06970706362754
IBP-MN-BB40	06970706362310	IBP-DT-AG40	06970706364383	IBP-FDB-EW40	06970706362761
IBP-FDA-BB40	06970706362327	IBP-BLT-AG40	06970706364390	IBP-ET-EW40	06970706362778
IBP-FDB-BB40	06970706362334	IBP-KTN-AG40	06970706364406	IBP-LT-EW40	06970706362785

IBP-ET-BB40	06970706362341	IBP-CL-AG40	06970706364413	IBP-SK-EW40	06970706362792
IBP-LT-BB40	06970706362358	IBP-MEK-AG40	06970706364420	IBP-SR-EW40	06970706362808
IBP-SK-BB40	06970706362365	IBP-HL-AG40	06970706364437	IBP-KR-EW40	06970706362815
IBP-SR-BB40	06970706362372	IBP-CSI-AG40	06970706364444	IBP-ME-EW40	06970706362822
IBP-KR-BB40	06970706362389	IBP-INF-AG40	06970706364451	IBP-MQ-2EW40	06941691904151
IBP-ME-BB40	06970706362396	IBP-MN-AG40	06970706364468	IBP-3MQ-3EW40	06941691907145
IBP-BR-BB40	06970706362402	IBP-FDA-AG40	06970706364475	IBPC-UT-MXT03	06970706366448
IBP-CM-BB40	06970706362419	IBP-FDB-AG40	06970706364482	IBPC-BB-MXT03	06970706366455
IBP-IG-BB40	06970706362426	IBP-ET-AG40	06970706364499	IBPC-ED-MXT03	06970706366462
IBP-GT-BB40	06970706362433	IBP-LT-AG40	06970706364505	IBPC-BD-MXT03	06970706366479
IBP-SA-BB40	06970706362440	IBP-SK-AG40	06970706364512	IBPC-PVB-MXT03	06970706366486
IBP-FS-BB40	06970706362457	IBP-SR-AG40	06970706364529	IBPC-MIR-MXT03	06970706366493
IBP-JJA-BB40	06970706362464	IBP-KR-AG40	06970706364536	IBPC-AG-MXT03	06941691954866
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IBP-HY-BB40	06970706362488	IBP-BR-AG40	06970706364550	IBPC-MXT-BB03	06941691947103
IBPA-DGA-2DGB03	06970706366400	IBP-CM-AG40	06970706364567	IBPC-ED-BB03	06941691947110
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IBPA-MQ-2MQ03	06970706366387	IBP-JJB-AG40	06970706364628	IBP-CA-MXT40	06941691971078
IBP-DT-USBAM15	06941691971085	IBP-DX-USBAM15	06941691971092	IBP-DGA-USBAM15	06941691971108
IBP-FDA-USBAM15	06941691971115	IBP-MQ-USBAM15	06941691971122	IBP-AM-USBAM15	06941691971139
IBP-NKA-USBAM15	06941691971146	IBP-PH-USBAM15	06941691971153	IBP-CSI-USBAM15	06941691971160
IBP-BR-USBAM15	06941691971177	IBP-DT-MD015	06941691971184	IBP-DX-MD015	06941691971191
IBP-DGA-MD015	06941691971207	IBP-FDA-MD015	06941691971214	IBP-MQ-MD015	06941691971221
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IBPC-MXT-BD03	06941691971269	IBPC-EW-UT03	06941691971276	IBPC-MXT-UT03	06941691971283
IBPC-BD-UT03	06941691971290	IBP-AM02-EW40	06941691977186	IBP-AM02-MXT40	06941691977179