

EU DECLARATION OF CONFORMITY

Document No. : DOC-005-01

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 : NIBP Cuff

Product Models: Please see the Annex I

Basic UDI - DI: 69416919ORANTECH06QZ

UMDNS Code : 11073

Classification(MDR Annex VIII) : Class I, Rule 1

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 1041:2008	ISO 81060-1:2007
EN ISO 10993-1:2018	EN ISO 10993-5:2009
EN ISO 10993-10:2010	IEC 62366 : 2015

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. 1st, 2021

Position: General Manager

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Annex I List of NIBP Cuffs

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
BP-10BS	6970706368039	BP-50NS-W10	6970706369425	BPD-80TD-WD08	6941691900887
BP-20BS	6970706368046	BP-60NS-W10	6970706369432	BPD-90TD-WD08	6941691900894
BP-30BS	6970706368053	BP-70NS-W10	6970706369449	BPD-20TD-W1011	6941691900900
BP-40BS	6970706368060	BP-80NS-W10	6970706369456	BPD-30TD-W1011	6941691900917
BP-50BS	6970706368077	BP-90NS-W10	6970706369463	BPD-40TD-W1011	6941691900924
BP-60BS	6970706368084	BP-10NS-W11	6970706369470	BPD-50TD-W1011	6941691900931
BP-70BS	6970706368091	BP-20NS-W11	6970706369487	BPD-60TD-W1011	6941691900948
BP-80BS	6970706368107	BP-30NS-W11	6970706369494	BPD-70TD-W1011	6941691900955
BP-90BS	6970706368114	BP-40NS-W11	6970706369500	BPD-80TD-W1011	6941691900962
BP-10BD	6970706368121	BP-50NS-W11	6970706369517	BPD-90TD-W1011	6941691900979
BP-20BD	6970706368138	BP-60NS-W11	6970706369524	BPD-20TD-WD11	6941691900986
BP-30BD	6970706368145	BP-70NS-W11	6970706369531	BPD-30TD-WD11	6941691900993
BP-40BD	6970706368152	BP-80NS-W11	6970706369548	BPD-40TD-WD11	6941691901006
BP-50BD	6970706368169	BP-90NS-W11	6970706369555	BPD-50TD-WD11	6941691901013
BP-60BD	6970706368176	BP-10NS-W37	6941691954965	BPD-60TD-WD11	6941691901020
BP-70BD	6970706368183	BP-20NS-W37	6941691954972	BPD-70TD-WD11	6941691901037
BP-80BD	6970706368190	BP-30NS-W37	6941691954989	BPD-80TD-WD11	6941691901044
BP-90BD	6970706368206	BP-40NS-W37	6941691954996	BPD-90TD-WD11	6941691901051
BP-10NS	6970706368213	BP-50NS-W37	6941691955009	BPD-11WS-W05P	6941691901068
BP-20NS	6970706368220	BP-60NS-W37	6941691955016	BPD-12WS-W05P	6941691901075

BP-30NS	6970706368237	BP-70NS-W37	6941691955023	BPD-13WS-W05P	6941691901082
BP-40NS	6970706368244	BP-80NS-W37	6941691955030	BPD-14WS-W05P	6941691901099
BP-50NS	6970706368251	BP-90NS-W37	6941691955047	BPD-15WS-W05P	6941691901105
BP-60NS	6970706368268	BP-50NS-W44	6941691960560	BPD-11WS-W36	6941691901112
BP-70NS	6970706368275	BP-10ND-WD08	6970706369562	BPD-12WS-W36	6941691901129
BP-80NS	6970706368282	BP-20ND-WD08	6970706369579	BPD-13WS-W36	6941691901136
BP-90NS	6970706368299	BP-30ND-WD08	6970706369586	BPD-14WS-W36	6941691901143
BP-10ND	6970706368305	BP-40ND-WD08	6970706369593	BPD-15WS-W36	6941691901150
BP-20ND	6970706368312	BP-50ND-WD08	6970706369609	BPD-20WS-W01P	6941691901167
BP-30ND	6970706368329	BP-60ND-WD08	6970706369616	BPD-30WS-W01P	6941691901174
BP-40ND	6970706368336	BP-70ND-WD08	6970706369623	BPD-40WS-W01P	6941691901181
BP-50ND	6970706368343	BP-80ND-WD08	6970706369630	BPD-50WS-W01P	6941691901198
BP-60ND	6970706368350	BP-90ND-WD08	6970706369647	BPD-60WS-W01P	6941691901204
BP-70ND	6970706368367	BP-10ND-W1011	6970706369654	BPD-70WS-W01P	6941691901211
BP-80ND	6970706368374	BP-20ND-W1011	6970706369661	BPD-80WS-W01P	6941691901228
BP-90ND	6970706368381	BP-30ND-W1011	6970706369678	BPD-90WS-W01P	6941691901235
BP-10BS-W01M	6970706368398	BP-40ND-W1011	6970706369685	BPD-20WS-W08	6941691901242
BP-20BS-W01M	6970706368404	BP-50ND-W1011	6970706369692	BPD-30WS-W08	6941691901259
BP-30BS-W01M	6970706368411	BP-60ND-W1011	6970706369708	BPD-40WS-W08	6941691901266
BP-40BS-W01M	6970706368428	BP-70ND-W1011	6970706369715	BPD-50WS-W08	6941691901273
BP-50BS-W01M	6970706368435	BP-80ND-W1011	6970706369722	BPD-60WS-W08	6941691901280
BP-60BS-W01M	6970706368442	BP-90ND-W1011	6970706369739	BPD-70WS-W08	6941691901297

BP-70BS-W01M	6970706368459	BP-10ND-WD11	6970706369746	BPD-80WS-W08	6941691901303
BP-80BS-W01M	6970706368466	BP-20ND-WD11	6970706369753	BPD-90WS-W08	6941691901310
BP-90BS-W01M	6970706368473	BP-30ND-WD11	6970706369760	BPD-20WS-W10	6941691901327
BP-10BS-W03P	6970706368480	BP-40ND-WD11	6970706369777	BPD-30WS-W10	6941691901334
BP-20BS-W03P	6970706368497	BP-50ND-WD11	6970706369784	BPD-40WS-W10	6941691901341
BP-30BS-W03P	6970706368503	BP-60ND-WD11	6970706369791	BPD-50WS-W10	6941691901358
BP-40BS-W03P	6970706368510	BP-70ND-WD11	6970706369807	BPD-60WS-W10	6941691901365
BP-50BS-W03P	6970706368527	BP-80ND-WD11	6970706369814	BPD-70WS-W10	6941691901372
BP-60BS-W03P	6970706368534	BP-90ND-WD11	6970706369821	BPD-80WS-W10	6941691901389
BP-70BS-W03P	6970706368541	BP-50ND-W38	6941691958574	BPD-90WS-W10	6941691901396
BP-80BS-W03P	6970706368558	BP-30ND-WD08-L180	6970706369586	BPD-20WS-W11	6941691901402
BP-90BS-W03P	6970706368565	BP-40ND-WD08-L180	6970706369593	BPD-30WS-W11	6941691901419
BP-10BS-W08	6970706368572	BP-50ND-WD08-L180	6970706369609	BPD-40WS-W11	6941691901426
BP-20BS-W08	6970706368589	BP-70ND-WD08-L180	6970706369623	BPD-50WS-W11	6941691901433
BP-30BS-W08	6970706368596	BP-20ND-W1011-L180	6970706369661	BPD-60WS-W11	6941691901440
BP-40BS-W08	6970706368602	BP-30ND-W1011-L180	6970706369678	BPD-70WS-W11	6941691901457
BP-50BS-W08	6970706368619	BP-40ND-W1011-L180	6970706369685	BPD-80WS-W11	6941691901464
BP-60BS-W08	6970706368626	BP-50ND-W1011-L180	6970706369692	BPD-90WS-W11	6941691901471
BP-70BS-W08	6970706368633	BP-60ND-W1011-L180	6970706369708	BPD-70WS-W03P	6941691947325
BP-80BS-W08	6970706368640	BP-70ND-W1011-L180	6970706369715	BPD-50WS-W03P	6941691947332
BP-90BS-W08	6970706368657	BP-80ND-W1011-L180	6970706369722	BPD-40WS-W03P	6941691947349
BP-10BS-W10	6970706368664	BP-90ND-W1011-L180	6970706369739	BPD-11WD-WD05P	6941691901488

BP-20BS-W10	6970706368671	BP-30ND-WD11-L180	6970706369760	BPD-12WD-WD05P	6941691901495
BP-30BS-W10	6970706368688	BP-40ND-WD11-L180	6970706369777	BPD-13WD-WD05P	6941691901501
BP-40BS-W10	6970706368695	BP-50ND-WD11-L180	6970706369784	BPD-14WD-WD05P	6941691901518
BP-50BS-W10	6970706368701	BP-70ND-WD11-L180	6970706369807	BPD-15WD-WD05P	6941691901525
BP-60BS-W10	6970706368718	BP-90ND-WD11-L180	6970706369821	BPD-20WD-WD08	6941691901532
BP-70BS-W10	6970706368725	BPD-11TS	6970706369838	BPD-30WD-WD08	6941691901549
BP-80BS-W10	6970706368732	BPD-12TS	6970706369845	BPD-40WD-WD08	6941691901556
BP-90BS-W10	6970706368749	BPD-13TS	6970706369852	BPD-50WD-WD08	6941691901563
BP-10BS-W11	6970706368756	BPD-14TS	6970706369869	BPD-60WD-WD08	6941691901570
BP-20BS-W11	6970706368763	BPD-15TS	6970706369876	BPD-70WD-WD08	6941691901587
BP-30BS-W11	6970706368770	BPD-20TS	6970706369883	BPD-80WD-WD08	6941691901594
BP-40BS-W11	6970706368787	BPD-30TS	6970706369890	BPD-90WD-WD08	6941691901600
BP-50BS-W11	6970706368794	BPD-14WS	6941691900122	BPD-20WD-W1011	6941691901617
BP-60BS-W11	6970706368800	BPD-15WS	6941691900139	BPD-30WD-W1011	6941691901624
BP-70BS-W11	6970706368817	BPD-20WS	6941691900146	BPD-40WD-W1011	6941691901631
BP-80BS-W11	6970706368824	BPD-30WS	6941691900153	BPD-50WD-W1011	6941691901648
BP-90BS-W11	6970706368831	BPD-40WS	6941691900160	BPD-60WD-W1011	6941691901655
BP-10BS-W37	6941691954873	BPD-50WS	6941691900177	BPD-70WD-W1011	6941691901662
BP-20BS-W37	6941691954880	BPD-60WS	6941691900184	BPD-80WD-W1011	6941691901679
BP-30BS-W37	6941691954897	BPD-70WS	6941691900191	BPD-90WD-W1011	6941691901686
BP-40BS-W37	6941691954903	BPD-80WS	6941691900207	BPD-20WD-WD11	6941691901693
BP-50BS-W37	6941691954910	BPD-90WS	6941691900214	BPD-30WD-WD11	6941691901709

BP-60BS-W37	6941691954927	BPD-11WD	6941691900221	BPD-40WD-WD11	6941691901716
BP-70BS-W37	6941691954934	BPD-12WD	6941691900238	BPD-50WD-WD11	6941691901723
BP-80BS-W37	6941691954941	BPD-13WD	6941691900245	BPD-60WD-WD11	6941691901730
BP-90BS-W37	6941691954958	BPD-14WD	6941691900252	BPD-70WD-WD11	6941691901747
BP-50BS-W44	6941691957980	BPD-15WD	6941691900269	BPD-80WD-WD11	6941691901754
BP-10BD-WD08	6970706368848	BPD-20WD	6941691900276	BPD-90WD-WD11	6941691901761
BP-20BD-WD08	6970706368855	BPD-30WD	6941691900283	BPD-30WD-W38	6941691958109
BP-30BD-WD08	6970706368862	BPD-40WD	6941691900290	BPD-20WD-W38	6941691958413
BP-40BD-WD08	6970706368879	BPD-50WD	6941691900306	BPD-40WD-W38	6941691958420
BP-50BD-WD08	6970706368886	BPD-60WD	6941691900313	BPD-50WD-W38	6941691958437
BP-60BD-WD08	6970706368893	BPD-70WD	6941691900320	BPD-60WD-W38	6941691958444
BP-70BD-WD08	6970706368909	BPD-80WD	6941691900337	BPD-70WD-W38	6941691958451
BP-80BD-WD08	6970706368916	BPD-90WD	6941691900344	BPD-80WD-W38	6941691958468
BP-90BD-WD08	6970706368923	BPD-11TS-W05P	6941691900351	BPD-90WD-W38	6941691958475
BP-10BD-W1011	6970706368930	BPD-12TS-W05P	6941691900368	BPD-11WD-WD34	6941691958482
BP-20BD-W1011	6970706368947	BPD-13TS-W05P	6941691900375	BPD-12WD-WD34	6941691958499
BP-30BD-W1011	6970706368954	BPD-14TS-W05P	6941691900382	BPD-13WD-WD34	6941691958505
BP-40BD-W1011	6970706368961	BPD-15TS-W05P	6941691900399	BPD-14WD-WD34	6941691958512
BP-50BD-W1011	6970706368978	BPD-11TS-W36	6941691900405	BPD-15WD-WD34	6941691958529
BP-60BD-W1011	6970706368985	BPD-12TS-W36	6941691900412	BPD-20WD-WD08-L180	6941691901532
BP-70BD-W1011	6970706368992	BPD-13TS-W36	6941691900429	BPD-30WD-WD08-L180	6941691901549
BP-80BD-W1011	6970706369005	BPD-14TS-W36	6941691900436	BPD-40WD-WD08-L180	6941691901556

BP-90BD-W1011	6970706369012	BPD-15TS-W36	6941691900443	BPD-50WD-WD08-L180	6941691901563
BP-10BD-WD11	6970706369029	BPD-20TS-W01P	6941691900450	BPD-60WD-WD08-L180	6941691901570
BP-20BD-WD11	6970706369036	BPD-30TS-W01P	6941691900467	BPD-70WD-WD08-L180	6941691901587
BP-30BD-WD11	6970706369043	BPD-40TS-W01P	6941691900474	BPD-80WD-WD08-L180	6941691901594
BP-40BD-WD11	6970706369050	BPD-50TS-W01P	6941691900481	BPD-90WD-WD08-L180	6941691901600
BP-50BD-WD11	6970706369067	BPD-60TS-W01P	6941691900498	BPD-20WD-W1011-L180	6941691901617
BP-60BD-WD11	6970706369074	BPD-70TS-W01P	6941691900504	BPD-30WD-W1011-L180	6941691901624
BP-70BD-WD11	6970706369081	BPD-80TS-W01P	6941691900511	BPD-40WD-W1011-L180	6941691901631
BP-80BD-WD11	6970706369098	BPD-90TS-W01P	6941691900528	BPD-50WD-W1011-L180	6941691901648
BP-90BD-WD11	6970706369104	BPD-20TS-W08	6941691900535	BPD-60WD-W1011-L180	6941691901655
BP-30BD-W38	6941691957898	BPD-30TS-W08	6941691900542	BPD-70WD-W1011-L180	6941691901662
BP-50BD-W38	6941691958659	BPD-40TS-W08	6941691900559	BPD-80WD-W1011-L180	6941691901679
BP-90BD-W38	6941691958697	BPD-50TS-W08	6941691900566	BPD-90WD-W1011-L180	6941691901686
BP-10NS-W01M	6970706369111	BPD-60TS-W08	6941691900573	BPD-20WD-WD11-L180	6941691901693
BP-20NS-W01M	6970706369128	BPD-70TS-W08	6941691900580	BPD-30WD-WD11-L180	6941691901709
BP-30NS-W01M	6970706369135	BPD-80TS-W08	6941691900597	BPD-40WD-WD11-L180	6941691901716
BP-40NS-W01M	6970706369142	BPD-90TS-W08	6941691900603	BPD-50WD-WD11-L180	6941691901723
BP-50NS-W01M	6970706369159	BPD-20TS-W10	6941691900610	BPD-60WD-WD11-L180	6941691901730
BP-60NS-W01M	6970706369166	BPD-30TS-W10	6941691900627	BPD-70WD-WD11-L180	6941691901747
BP-70NS-W01M	6970706369173	BPD-40TS-W10	6941691900634	BPD-80WD-WD11-L180	6941691901754
BP-80NS-W01M	6970706369180	BPD-50TS-W10	6941691900641	BPD-90WD-WD11-L180	6941691901761
BP-90NS-W01M	6970706369197	BPD-60TS-W10	6941691900658	BPD-40TS	6970706369906

BP-10NS-W03P	6970706369203	BPD-70TS-W10	6941691900665	BPD-50TS	6970706369913
BP-20NS-W03P	6970706369210	BPD-80TS-W10	6941691900672	BPD-60TS	6970706369920
BP-30NS-W03P	6970706369227	BPD-90TS-W10	6941691900689	BPD-70TS	6970706369937
BP-40NS-W03P	6970706369234	BPD-20TS-W11	6941691900696	BPD-80TS	6970706369944
BP-50NS-W03P	6970706369241	BPD-30TS-W11	6941691900702	BPD-90TS	6970706369951
BP-60NS-W03P	6970706369258	BPD-40TS-W11	6941691900719	BPD-11TD	6970706369968
BP-70NS-W03P	6970706369265	BPD-50TS-W11	6941691900726	BPD-12TD	6970706369975
BP-80NS-W03P	6970706369272	BPD-60TS-W11	6941691900733	BPD-13TD	6970706369982
BP-90NS-W03P	6970706369289	BPD-70TS-W11	6941691900740	BPD-14TD	6970706369999
BP-10NS-W08	6970706369296	BPD-80TS-W11	6941691900757	BPD-15TD	6941691900009
BP-20NS-W08	6970706369302	BPD-90TS-W11	6941691900764	BPD-20TD	6941691900016
BP-30NS-W08	6970706369319	BPD-11TD-WD05P	6941691900771	BPD-30TD	6941691900023
BP-40NS-W08	6970706369326	BPD-12TD-WD05P	6941691900788	BPD-40TD	6941691900030
BP-50NS-W08	6970706369333	BPD-13TD-WD05P	6941691900795	BPD-50TD	6941691900047
BP-60NS-W08	6970706369340	BPD-14TD-WD05P	6941691900801	BPD-60TD	6941691900054
BP-70NS-W08	6970706369357	BPD-15TD-WD05P	6941691900818	BPD-70TD	6941691900061
BP-80NS-W08	6970706369364	BPD-20TD-WD08	6941691900825	BPD-80TD	6941691900078
BP-90NS-W08	6970706369371	BPD-30TD-WD08	6941691900832	BPD-90TD	6941691900085
BP-10NS-W10	6970706369388	BPD-40TD-WD08	6941691900849	BPD-11WS	6941691900092
BP-20NS-W10	6970706369395	BPD-50TD-WD08	6941691900856	BPD-12WS	6941691900108
BP-30NS-W10	6970706369401	BPD-60TD-WD08	6941691900863	BPD-13WS	6941691900115
BP-40NS-W10	6970706369418	BPD-70TD-WD08	6941691900870		

