

EU DECLARATION OF CONFORMITY

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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 : Disposable SpO2 Sensor

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH13QW

UMDNS Code : 17594

Classification - Annex IX : Class IIb , Rule10

Conformity Assessment Route : Annex II

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 transposition national law, the provisions of Council Directive 93/42/EEC 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 ISO13485: 2016

EN 1041:2008+A1:2013

EN ISO 14971:2019

EN ISO 15223-1: 2021

DIRECTIVE 2011/65/EU

EN ISO 10993-5:2009

EN ISO 10993-10:2010

EN62366-1:2015

EN ISO 80601-2-61:2011

IEC 60601-1-2: 2014

IEC 60601-1:2005/A1:2012

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

CE mark: 

EC Certificate No : G1 098084 0003 Rev. 01

Valid Date From : 2020-01-10

Valid Date Until : 2024-05-26

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Confirmation Letter No. : CL 098084 0005 Rev. 00

Valid Date From : 2024-05-26

Valid Date Until : 2028-12-31

Place, Date of Issue :

Signature :



Shenzhen, Jun. 25th, 2024

Position: General Manager

Annex I List of SpO2 Sensor

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
SSD-001-W09A	06941691927099	SSD-001-S09PI	06941691908159	SSD-001-S09AN	06941691908374
SSD-001XC-W09A	06941691927105	SSD-001XC-S09PI	06941691908160	SSD-001XC-S09AN	06941691908375
SSD-005M-W09A	06941691927112	SSD-005M-S09PI	06941691908161	SSD-005M-S09AN	06941691908376
SSD-005RB-W09A	06941691927129	SSD-005RB-S09PI	06941691908162	SSD-005RB-S09AN	06941691908377
SSD-006M-W09A	06941691927136	SSD-006M-S09PI	06941691908163	SSD-006M-S09AN	06941691908378
SSD-006RB-W09A	06941691927143	SSD-006RB-S09PI	06941691908164	SSD-006RB-S09AN	06941691908379
SSD-007RB-W09A	06941691927150	SSD-007RB-S09PI	06941691908165	SSD-007RB-S09AN	06941691908380
SSD-012-W09A	06941691927167	SSD-012-S09PI	06941691908166	SSD-012-S09AN	06941691908381
SSD-013-W09A	06941691927174	SSD-013-S09PI	06941691908167	SSD-013-S09AN	06941691908382
SSD-018-W09A	06941691927181	SSD-018-S09PI	06941691908168	SSD-018-S09AN	06941691908383
SSD-019-W09A	06941691927198	SSD-019-S09PI	06941691908169	SSD-019-S09AN	06941691908384
SSD-024-W09A	06941691927204	SSD-024-S09PI	06941691908170	SSD-024-S09AN	06941691908385
SSD-030-W09A	06941691927211	SSD-030-S09PI	06941691908171	SSD-030-S09AN	06941691908386

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SSD-032-W09A	06941691927228	SSD-032-S09PI	06941691908172	SSD-032-S09AN	06941691908387
SSD-034-W09A	06941691927235	SSD-034-S09PI	06941691908173	SSD-034-S09AN	06941691908388
SSD-036-W09A	06941691927242	SSD-036-S09PI	06941691908174	SSD-036-S09AN	06941691908389
SSD-039-W09A	06941691927259	SSD-039-S09PI	06941691908175	SSD-039-S09AN	06941691908390
SSD-040-W09A	06941691927266	SSD-040-S09PI	06941691908176	SSD-040-S09AN	06941691908391
SSD-043-W09A	06941691927273	SSD-043-S09PI	06941691908177	SSD-043-S09AN	06941691908392
SSD-058-W09A	06941691927280	SSD-058-S09PI	06941691908178	SSD-058-S09AN	06941691908393
SSD-064D-W09A	06941691927297	SSD-064D-S09PI	06941691908179	SSD-064D-S09AN	06941691908394
SSD-073D-W09A	06941691927303	SSD-073D-S09PI	06941691908180	SSD-073D-S09AN	06941691908395
SSD-079-W09A	06941691927310	SSD-079-S09PI	06941691908181	SSD-079-S09AN	06941691908396
SSD-031-W09A	06941691954668	SSD-001-W09AN	06941691908182	SSD-018-W09I	06941691908397
SSD-001-W09P	06941691927327	SSD-001XC-W09AN	06941691908183	SSD-001-W09I	06941691908398
SSD-001XC-W09P	06941691927334	SSD-005M-W09AN	06941691908184	SSD-001XC-W09I	06941691908399
SSD-005M-W09P	06941691927341	SSD-005RB-W09AN	06941691908185	SSD-005M-W09I	06941691908400
SSD-005RB-W09P	06941691927358	SSD-006M-W09AN	06941691908186	SSD-005RB-W09I	06941691908401
SSD-006M-W09P	06941691927365	SSD-006RB-W09AN	06941691908187	SSD-006M-W09I	06941691908402
SSD-006RB-W09P	06941691927372	SSD-007RB-W09AN	06941691908188	SSD-006RB-W09I	06941691908403
SSD-007RB-W09P	06941691927389	SSD-012-W09AN	06941691908189	SSD-007RB-W09I	06941691908404
SSD-012-W09P	06941691927396	SSD-013-W09AN	06941691908190	SSD-012-W09I	06941691908405
SSD-013-W09P	06941691927402	SSD-018-W09AN	06941691908191	SSD-013-W09I	06941691908406
SSD-018-W09P	06941691927419	SSD-019-W09AN	06941691908192	SSD-018-W09I	06941691908407

SSD-019-W09P	06941691927426	SSD-024-W09AN	06941691908193	SSD-019-W09I	06941691908408
SSD-024-W09P	06941691927433	SSD-030-W09AN	06941691908194	SSD-024-W09I	06941691908409
SSD-030-W09P	06941691927440	SSD-032-W09AN	06941691908195	SSD-030-W09I	06941691908410
SSD-032-W09P	06941691927457	SSD-034-W09AN	06941691908196	SSD-032-W09I	06941691908411
SSD-034-W09P	06941691927464	SSD-036-W09AN	06941691908197	SSD-034-W09I	06941691908412
SSD-036-W09P	06941691927471	SSD-039-W09AN	06941691908198	SSD-036-W09I	06941691908413
SSD-039-W09P	06941691927488	SSD-040-W09AN	06941691908199	SSD-039-W09I	06941691908414
SSD-040-W09P	06941691927495	SSD-043-W09AN	06941691908200	SSD-040-W09I	06941691908415
SSD-043-W09P	06941691927501	SSD-058-W09AN	06941691908201	SSD-043-W09I	06941691908416
SSD-058-W09P	06941691927518	SSD-064D-W09AN	06941691908202	SSD-058-W09I	06941691908417
SSD-064D-W09P	06941691927525	SSD-073D-W09AN	06941691908203	SSD-064D-W09I	06941691908418
SSD-073D-W09P	06941691927532	SSD-079-W09I	06941691908204	SSD-073D-W09I	06941691908419
SSD-079-W09P	06941691927549	SSD-043-W16I	06941691908205	SSD-165RB-W09AN	06941691908420
SSD-043-W16P	06941691966241	SSD-165RB-W09I	06941691908206	SSD-043-S16AN	06941691908421
SSD-165RB-W09P	06941691968351	SSD-043-W16AN	06941691908207	SSD-165RB-S09AN	06941691908422
SSD-043-W16P	06941691966241	SSD-165RB-W09P	06941691908210	SSD-001XC-N09A	06941691975007
SSD-001XC-N09P	06941691975021	SSD-001XC-N09I	06941691908213	SSD-001XC-N09AN	06941691908428