

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

EU- 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+A1:2025

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

ISO 10993-5:2009

ISO 10993-10:2010

EN 62366-1:2015

ISO 80601-2-61:2017, COR1:2018

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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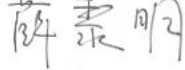
Add Zone#A,4F,1st Bld,7th Industrial Zone,Yulv Community,GongMing,Guangming New District,Shenzhen,China 518106

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, May. 12th, 2025

Position: General Manager

Annex I List of SpO2 Sensor

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
SSD-005RB-FH09	06941691981923	SSD-036-S09AN	06941691928164	SSD-018-W09I	06941691927648
SSD-001XC-FH09	06941691981916	SSD-034-S09AN	06941691928157	SSD-013-W09I	06941691927631
SSD-001-N09AN	06941691977384	SSD-032-S09AN	06941691928140	SSD-012-W09I	06941691927624
SSD-175-W09AN	06941691975618	SSD-030-S09AN	06941691928133	SSD-007RB-W09I	06941691927617
SSD-001XC-N09A	06941691975007	SSD-024-S09AN	06941691928126	SSD-006RB-W09I	06941691927600
SSD-001XC-N09AN	06941691974994	SSD-019-S09AN	06941691928119	SSD-005RB-W09I	06941691927587
SSD-001XC-N09I	06941691975014	SSD-018-S09AN	06941691928102	SSD-001XC-W09I	06941691927563
SSD-001XC-N09P	06941691975021	SSD-013-S09AN	06941691928096	SSD-001-W09I	06941691927556
SSD-165RB-S09AN	06941691973553	SSD-012-S09AN	06941691928089	SSD-079-W09P	06941691927549
SSD-165RB-W09P	06941691968351	SSD-007RB-S09AN	06941691928072	SSD-073D-W09P	06941691927532
SSD-165RB-W09I	06941691968344	SSD-006RB-S09AN	06941691928065	SSD-064D-W09P	06941691927525
SSD-165RB-W09AN	06941691968337	SSD-005RB-S09AN	06941691928041	SSD-058-W09P	06941691927518
SSD-043-S16PI	06941691966289	SSD-001XC-S09AN	06941691928027	SSD-043-W09P	06941691927501
SSD-043-S16AN	06941691966272	SSD-001-S09AN	06941691928010	SSD-040-W09P	06941691927495
SSD-043-W16AN	06941691966265	SSD-079-W09AN	06941691928003	SSD-039-W09P	06941691927488

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SSD-043-W16I	06941691966258	SSD-073D-W09AN	06941691927990	SSD-036-W09P	06941691927471
SSD-043-W16P	06941691966241	SSD-064D-W09AN	06941691927983	SSD-034-W09P	06941691927464
SSD-043-W16A	06941691966234	SSD-058-W09AN	06941691927976	SSD-032-W09P	06941691927457
SSD-031-W09A	06941691954668	SSD-043-W09AN	06941691927969	SSD-030-W09P	06941691927440
SSD-079-S09PI	06941691928461	SSD-040-W09AN	06941691927952	SSD-024-W09P	06941691927433
SSD-073D-S09PI	06941691928454	SSD-039-W09AN	06941691927945	SSD-019-W09P	06941691927426
SSD-064D-S09PI	06941691928447	SSD-036-W09AN	06941691927938	SSD-018-W09P	06941691927419
SSD-058-S09PI	06941691928430	SSD-034-W09AN	06941691927921	SSD-013-W09P	06941691927402
SSD-043-S09PI	06941691928423	SSD-032-W09AN	06941691927914	SSD-012-W09P	06941691927396
SSD-040-S09PI	06941691928416	SSD-030-W09AN	06941691927907	SSD-007RB-W09P	06941691927389
SSD-039-S09PI	06941691928409	SSD-024-W09AN	06941691927891	SSD-006RB-W09P	06941691927372
SSD-036-S09PI	06941691928393	SSD-019-W09AN	06941691927884	SSD-005RB-W09P	06941691927358
SSD-034-S09PI	06941691928386	SSD-018-W09AN	06941691927877	SSD-001XC-W09P	06941691927334
SSD-032-S09PI	06941691928379	SSD-013-W09AN	06941691927860	SSD-001-W09P	06941691927327
SSD-030-S09PI	06941691928362	SSD-012-W09AN	06941691927853	SSD-079-W09A	06941691927310
SSD-024-S09PI	06941691928355	SSD-007RB-W09AN	06941691927846	SSD-073D-W09A	06941691927303
SSD-019-S09PI	06941691928348	SSD-006RB-W09AN	06941691927839	SSD-064D-W09A	06941691927297
SSD-018-S09PI	06941691928331	SSD-005RB-W09AN	06941691927815	SSD-058-W09A	06941691927280
SSD-013-S09PI	06941691928324	SSD-001XC-W09AN	06941691927792	SSD-043-W09A	06941691927273
SSD-012-S09PI	06941691928317	SSD-001-W09AN	06941691927785	SSD-040-W09A	06941691927266
SSD-007RB-S09PI	06941691928300	SSD-079-W09I	06941691927778	SSD-039-W09A	06941691927259

SSD-006RB-S09PI	06941691928294	SSD-073D-W09I	06941691927761	SSD-036-W09A	06941691927242
SSD-005RB-S09PI	06941691928270	SSD-064D-W09I	06941691927754	SSD-034-W09A	06941691927235
SSD-001XC-S09PI	06941691928256	SSD-058-W09I	06941691927747	SSD-032-W09A	06941691927228
SSD-001-S09PI	06941691928249	SSD-043-W09I	06941691927730	SSD-030-W09A	06941691927211
SSD-079-S09AN	06941691928232	SSD-040-W09I	06941691927723	SSD-024-W09A	06941691927204
SSD-073D-S09AN	06941691928225	SSD-039-W09I	06941691927716	SSD-019-W09A	06941691927198
SSD-064D-S09AN	06941691928218	SSD-036-W09I	06941691927709	SSD-018-W09A	06941691927181
SSD-058-S09AN	06941691928201	SSD-034-W09I	06941691927693	SSD-013-W09A	06941691927174
SSD-043-S09AN	06941691928195	SSD-032-W09I	06941691927686	SSD-012-W09A	06941691927167
SSD-040-S09AN	06941691928188	SSD-030-W09I	06941691927679	SSD-007RB-W09A	06941691927150
SSD-039-S09AN	06941691928171	SSD-024-W09I	06941691927662	SSD-006RB-W09A	06941691927143
SSD-001-W09A	06941691927099	SSD-019-W09I	06941691927655	SSD-005RB-W09A	06941691927129
SSD-001XC-W09A	06941691927105	SSD-165RB-W09A	06941691983316		