

## ***EU DECLARATION OF CONFORMITY***

**Document No. :** DOC-002-02

**Rev:** A2

**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 Annex II (EU) 2015/863

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

**Orantech Inc.**

**T** +86-755 2369 9939 **F** +86-755 2324 3594 **E** info@orantech.com **W** www.orantech.com

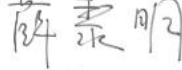
**Add** Zone#A,4F,1st Bld,7th Industrial Zone,Yulv Community,GongMing,Guangming New District,Shenzhen,China 518106

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, Aug. 27<sup>th</sup>, 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   | 06941691928249 | SSD-001XC-N09I  | 06941691975014 |
| SSD-001XC-W09A | 06941691927105 | SSD-001XC-S09PI | 06941691928256 | SSD-001-S09AN   | 06941691928010 |
| SSD-005M-W09A  | 06941691927112 | SSD-005M-S09PI  | 06941691928263 | SSD-001XC-S09AN | 06941691928027 |
| SSD-005RB-W09A | 06941691927129 | SSD-005RB-S09PI | 06941691928270 | SSD-005M-S09AN  | 06941691928034 |
| SSD-006M-W09A  | 06941691927136 | SSD-006M-S09PI  | 06941691928287 | SSD-005RB-S09AN | 06941691928041 |
| SSD-006RB-W09A | 06941691927143 | SSD-006RB-S09PI | 06941691928294 | SSD-006M-S09AN  | 06941691928058 |
| SSD-007RB-W09A | 06941691927150 | SSD-007RB-S09PI | 06941691928300 | SSD-006RB-S09AN | 06941691928065 |
| SSD-012-W09A   | 06941691927167 | SSD-012-S09PI   | 06941691928317 | SSD-007RB-S09AN | 06941691928072 |
| SSD-013-W09A   | 06941691927174 | SSD-013-S09PI   | 06941691928324 | SSD-012-S09AN   | 06941691928089 |
| SSD-018-W09A   | 06941691927181 | SSD-018-S09PI   | 06941691928331 | SSD-013-S09AN   | 06941691928096 |
| SSD-019-W09A   | 06941691927198 | SSD-019-S09PI   | 06941691928348 | SSD-018-S09AN   | 06941691928102 |
| SSD-024-W09A   | 06941691927204 | SSD-024-S09PI   | 06941691928355 | SSD-019-S09AN   | 06941691928119 |
| SSD-030-W09A   | 06941691927211 | SSD-030-S09PI   | 06941691928362 | SSD-024-S09AN   | 06941691928126 |
| SSD-032-W09A   | 06941691927228 | SSD-032-S09PI   | 06941691928379 | SSD-030-S09AN   | 06941691928133 |
| SSD-034-W09A   | 06941691927235 | SSD-034-S09PI   | 06941691928386 | SSD-032-S09AN   | 06941691928140 |

**Orantech Inc.**

**T** +86-755 2369 9939 **F** +86-755 2324 3594 **E** info@orantech.com **W** www.orantech.com

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

|                |                |                 |                |                |                |
|----------------|----------------|-----------------|----------------|----------------|----------------|
| SSD-036-W09A   | 06941691927242 | SSD-036-S09PI   | 06941691928393 | SSD-034-S09AN  | 06941691928157 |
| SSD-039-W09A   | 06941691927259 | SSD-039-S09PI   | 06941691928409 | SSD-036-S09AN  | 06941691928164 |
| SSD-040-W09A   | 06941691927266 | SSD-040-S09PI   | 06941691928416 | SSD-039-S09AN  | 06941691928171 |
| SSD-043-W09A   | 06941691927273 | SSD-043-S09PI   | 06941691928423 | SSD-040-S09AN  | 06941691928188 |
| SSD-058-W09A   | 06941691927280 | SSD-058-S09PI   | 06941691928430 | SSD-043-S09AN  | 06941691928195 |
| SSD-064D-W09A  | 06941691927297 | SSD-064D-S09PI  | 06941691928447 | SSD-058-S09AN  | 06941691928201 |
| SSD-073D-W09A  | 06941691927303 | SSD-073D-S09PI  | 06941691928454 | SSD-064D-S09AN | 06941691928218 |
| SSD-079-W09A   | 06941691927310 | SSD-079-S09PI   | 06941691928461 | SSD-073D-S09AN | 06941691928225 |
| SSD-031-W09A   | 06941691954668 | SSD-001-W09AN   | 06941691927785 | SSD-079-S09AN  | 06941691928232 |
| SSD-001-W09P   | 06941691927327 | SSD-001XC-W09AN | 06941691927792 | SSD-001-W09I   | 06941691927556 |
| SSD-001XC-W09P | 06941691927334 | SSD-005M-W09AN  | 06941691927808 | SSD-001XC-W09I | 06941691927563 |
| SSD-005M-W09P  | 06941691927341 | SSD-005RB-W09AN | 06941691927815 | SSD-005M-W09I  | 06941691927570 |
| SSD-005RB-W09P | 06941691927358 | SSD-006M-W09AN  | 06941691927822 | SSD-005RB-W09I | 06941691927587 |
| SSD-006M-W09P  | 06941691927365 | SSD-006RB-W09AN | 06941691927839 | SSD-006M-W09I  | 06941691927594 |
| SSD-006RB-W09P | 06941691927372 | SSD-007RB-W09AN | 06941691927846 | SSD-006RB-W09I | 06941691927600 |
| SSD-007RB-W09P | 06941691927389 | SSD-012-W09AN   | 06941691927853 | SSD-007RB-W09I | 06941691927617 |
| SSD-012-W09P   | 06941691927396 | SSD-013-W09AN   | 06941691927860 | SSD-012-W09I   | 06941691927624 |
| SSD-013-W09P   | 06941691927402 | SSD-018-W09AN   | 06941691927877 | SSD-013-W09I   | 06941691927631 |
| SSD-018-W09P   | 06941691927419 | SSD-019-W09AN   | 06941691927884 | SSD-018-W09I   | 06941691927648 |
| SSD-019-W09P   | 06941691927426 | SSD-024-W09AN   | 06941691927891 | SSD-019-W09I   | 06941691927655 |
| SSD-024-W09P   | 06941691927433 | SSD-030-W09AN   | 06941691927907 | SSD-024-W09I   | 06941691927662 |

|                 |                |                |                |                 |                |
|-----------------|----------------|----------------|----------------|-----------------|----------------|
| SSD-030-W09P    | 06941691927440 | SSD-032-W09AN  | 06941691927914 | SSD-030-W09I    | 06941691927679 |
| SSD-032-W09P    | 06941691927457 | SSD-034-W09AN  | 06941691927921 | SSD-032-W09I    | 06941691927686 |
| SSD-034-W09P    | 06941691927464 | SSD-036-W09AN  | 06941691927938 | SSD-034-W09I    | 06941691927693 |
| SSD-036-W09P    | 06941691927471 | SSD-039-W09AN  | 06941691927945 | SSD-036-W09I    | 06941691927709 |
| SSD-039-W09P    | 06941691927488 | SSD-040-W09AN  | 06941691927952 | SSD-039-W09I    | 06941691927716 |
| SSD-040-W09P    | 06941691927495 | SSD-043-W09AN  | 06941691927969 | SSD-040-W09I    | 06941691927723 |
| SSD-043-W09P    | 06941691927501 | SSD-058-W09AN  | 06941691927976 | SSD-043-W09I    | 06941691927730 |
| SSD-058-W09P    | 06941691927518 | SSD-064D-W09AN | 06941691927983 | SSD-058-W09I    | 06941691927747 |
| SSD-064D-W09P   | 06941691927525 | SSD-073D-W09AN | 06941691927990 | SSD-064D-W09I   | 06941691927754 |
| SSD-073D-W09P   | 06941691927532 | SSD-079-W09I   | 06941691927778 | SSD-073D-W09I   | 06941691927761 |
| SSD-079-W09P    | 06941691927549 | SSD-043-W16I   | 06941691966258 | SSD-165RB-W09AN | 06941691968337 |
| SSD-043-W16P    | 06941691966241 | SSD-165RB-W09I | 06941691968344 | SSD-043-S16AN   | 06941691966272 |
| SSD-001XC-N09P  | 06941691975021 | SSD-043-W16AN  | 06941691966265 | SSD-165RB-S09AN | 06941691973553 |
| SSD-001XC-N09AN | 06941691974994 | SSD-165RB-W09P | 06941691968351 | SSD-001XC-N09A  | 06941691975007 |