

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

**Document No. :** DOC-001-04

**Rev:** B7

**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 :** Patient Cables (SPO2 Adapter Cables )

**Product Models :** Please see the Annex I

**Basic UDI - DI:** 69416919ORANTECH07R3

**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: 2021

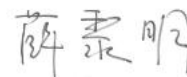
Directive 2011/65/EU Annex II (EU) 2015/863

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

**CE mark :** 

**Place, Date of Issue :**

**Signature :**



Shenzhen, Jan. 9<sup>th</sup>, 2025

**Position:** General Manager

**Annex I List Of SPO2 Adapter Cables**

| Model          | UDI-DI         | Model         | UDI-DI         | Model         | UDI-DI         |
|----------------|----------------|---------------|----------------|---------------|----------------|
| SA-176RB-30LS  | 06941691981909 | SA-009RB-12ML | 06941691946939 | SA-057X-30    | 06941691925651 |
| SA-176RB-30    | 06941691981893 | SA-009RB-03LS | 06941691946922 | SA-056-24     | 06941691925644 |
| SA-167RB-36RD  | 06941691981756 | SA-045RB-30LS | 06941691946915 | SA-055-24     | 06941691925637 |
| SA-167RB-24RD  | 06941691981510 | SA-009RB-12LS | 06941691946908 | SA-054-24     | 06941691925620 |
| SA-167RB-15RD  | 06941691981749 | SA-009RB-30LS | 06941691946892 | SA-053RB-24ML | 06941691925613 |
| SA-167RB-05RD  | 06941691981732 | SA-040-24NE   | 06941691927068 | SA-053RB-24LP | 06941691925606 |
| SA-026RB-21RD  | 06941691982234 | SA-015M-30LS  | 06941691927051 | SA-053RB-24LS | 06941691925590 |
| SA-001-001-24  | 06941691981688 | SA-026X-30XN  | 06941691927044 | SA-053RB-24   | 06941691925583 |
| SA-024M-30ML   | 06941691981053 | SA-158-24     | 06941691927037 | SA-053M-24ML  | 06941691925576 |
| SA-008RB-40    | 06941691968931 | SA-001X-03XN  | 06941691927020 | SA-053M-24LP  | 06941691925569 |
| SA-175RB-03LS  | 06941691980407 | SA-156-06     | 06941691927013 | SA-053M-24LS  | 06941691925552 |
| SA-171-20      | 06941691980803 | SA-154-24     | 06941691927006 | SA-053M-24    | 06941691925545 |
| SA-124-24NE    | 06941691980285 | SA-153X-24XC  | 06941691926993 | SA-053X-24XC  | 06941691925538 |
| SA-026RB-30    | 06941691980636 | SA-153X-30    | 06941691926986 | SA-053X-30    | 06941691925521 |
| SA-008RB-24-V3 | 06941691980414 | SA-152-24     | 06941691926979 | SA-053-24     | 06941691925514 |
| SA-175RB-12LS  | 06941691975717 | SA-151-24     | 06941691926962 | SA-052M-24ML  | 06941691925507 |
| SA-162RB-30    | 06941691977490 | SA-149-24     | 06941691926955 | SA-052M-24LP  | 06941691925491 |
| SA-040-90      | 06941691978770 | SA-148-24     | 06941691926948 | SA-052M-24LS  | 06941691925484 |
| SA-040-60      | 06941691978763 | SA-146-24     | 06941691926931 | SA-052M-24    | 06941691925477 |

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| SA-040-30       | 06941691978756 | SA-144-24     | 06941691926924 | SA-052X-24XC  | 06941691925460 |
| SA-040-10       | 06941691978749 | SA-143-24     | 06941691926917 | SA-052X-30    | 06941691925453 |
| SA-005RB-24RD   | 06941691977292 | SA-142-24     | 06941691926900 | SA-052-24     | 06941691925446 |
| SA-165RB-12RD   | 06941691977117 | SA-141-24     | 06941691926894 | SA-051M-24ML  | 06941691925439 |
| SA-165RB-03LS   | 06941691977100 | SA-140-24     | 06941691926887 | SA-051M-24LP  | 06941691925422 |
| SA-026RB-36RD   | 06941691977094 | SA-139-24     | 06941691926870 | SA-051M-24LS  | 06941691925415 |
| SA-053RB-30RD   | 06941691977087 | SA-138RB-24ML | 06941691926863 | SA-051M-24    | 06941691925408 |
| SA-045RB-36RD   | 06941691977070 | SA-138RB-24LP | 06941691926856 | SA-050M-24ML  | 06941691925392 |
| SA-045RB-15RD   | 06941691977063 | SA-138RB-24LS | 06941691926849 | SA-050M-24LP  | 06941691925385 |
| SA-015RB-36RD   | 06941691977056 | SA-138RB-24   | 06941691926832 | SA-050M-24LS  | 06941691925378 |
| SA-015RB-15RD   | 06941691977049 | SA-136-24     | 06941691926825 | SA-050M-24    | 06941691925361 |
| SA-024M-36RD    | 06941691977032 | SA-135-24     | 06941691926818 | SA-050-24     | 06941691925354 |
| SA-024M-15RD    | 06941691977025 | SA-134-24     | 06941691926801 | SA-049RB-24ML | 06941691925347 |
| SA-008RB-36RD   | 06941691977018 | SA-133-24     | 06941691926795 | SA-049RB-24LP | 06941691925330 |
| SA-165RB-36RD   | 06941691976998 | SA-132X-24XC  | 06941691926788 | SA-049RB-24LS | 06941691925323 |
| SA-165RB-15RD   | 06941691976981 | SA-132X-30    | 06941691926771 | SA-049RB-24   | 06941691925316 |
| SA-009RB-36RD   | 06941691976974 | SA-132-24     | 06941691926764 | SA-049M-24ML  | 06941691925309 |
| SA-009RB-03RD   | 06941691976967 | SA-131-24     | 06941691926757 | SA-049M-24LP  | 06941691925293 |
| SA-001X-001X-48 | 06941691976950 | SA-130M-16ML  | 06941691926740 | SA-049M-24LS  | 06941691925286 |
| SA-001-001-60   | 06941691976936 | SA-130M-24LP  | 06941691926733 | SA-049M-24    | 06941691925279 |
| SA-053RB-77     | 06941691976929 | SA-130M-12LS  | 06941691926726 | SA-049-24     | 06941691925262 |
| SA-015RB-40     | 06941691976912 | SA-130M-24    | 06941691926719 | SA-048M-24ML  | 06941691925255 |

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| SA-015RB-12   | 06941691976905 | SA-129-24     | 06941691926702 | SA-048M-24LP | 06941691925248 |
| SA-009RB-40   | 06941691976899 | SA-128-24     | 06941691926696 | SA-048M-24LS | 06941691925231 |
| SA-009RB-30   | 06941691976882 | SA-127-24     | 06941691926689 | SA-048M-24   | 06941691925224 |
| SA-009RB-03   | 06941691976875 | SA-125RB-24ML | 06941691926672 | SA-048-24    | 06941691925217 |
| SA-008RB-36   | 06941691976868 | SA-125RB-24LP | 06941691926665 | SA-047X-24XC | 06941691925200 |
| SA-008RB-12   | 06941691976851 | SA-125RB-24LS | 06941691926658 | SA-047X-30   | 06941691925194 |
| SA-008RB-03   | 06941691976844 | SA-125RB-24   | 06941691926641 | SA-046-30    | 06941691925187 |
| SA-167RB-30LS | 06941691976837 | SA-124-24     | 06941691926634 | SA-045M-30ML | 06941691925170 |
| SA-045RB-30RD | 06941691975588 | SA-123RB-24ML | 06941691926627 | SA-045M-24LP | 06941691925163 |
| SA-015-30LS   | 06941691975083 | SA-123RB-24LP | 06941691926610 | SA-045M-30LS | 06941691925156 |
| SA-015RB-24RD | 06941691975540 | SA-123RB-24LS | 06941691926603 | SA-045M-24   | 06941691925149 |
| SA-052-12     | 06941691975502 | SA-123RB-24   | 06941691926597 | SA-045X-24XC | 06941691925132 |
| SA-053-12     | 06941691975496 | SA-122RB-24ML | 06941691926580 | SA-045X-24XN | 06941691925125 |
| SA-167RB-24ML | 06941691975090 | SA-122RB-24LP | 06941691926573 | SA-045X-30   | 06941691925118 |
| SA-167RB-36ML | 06941691975526 | SA-122RB-24LS | 06941691926566 | SA-045-30    | 06941691925101 |
| SA-006RB-03RD | 06941691973744 | SA-122RB-24   | 06941691926559 | SA-044-30    | 06941691925095 |
| SA-005RB-12LS | 06941691973874 | SA-122X-24XC  | 06941691926542 | SA-041-24    | 06941691925088 |
| SA-171-12     | 06941691970132 | SA-122X-30    | 06941691926535 | SA-039-24    | 06941691925071 |
| SA-023-24LP   | 06941691968900 | SA-121-24     | 06941691926528 | SA-038-24    | 06941691925064 |
| SA-015X-30XC  | 06941691970125 | SA-120-24     | 06941691926511 | SA-037-24    | 06941691925057 |
| SA-008RB-30   | 06941691968924 | SA-119X-24XC  | 06941691926504 | SA-036-24    | 06941691925040 |
| SA-005RB-03RD | 06941691969969 | SA-119X-30    | 06941691926498 | SA-035-24    | 06941691925033 |

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| SA-155-24     | 06941691968887 | SA-118X-24XC | 06941691926481 | SA-033-24     | 06941691925026 |
| SA-162RB-24LS | 06941691968320 | SA-118X-30   | 06941691926474 | SA-029-24     | 06941691925019 |
| SA-008RB-30RD | 06941691968061 | SA-117-24    | 06941691926467 | SA-028RB-24ML | 06941691925002 |
| SA-009RB-24RD | 06941691967118 | SA-116-24    | 06941691926450 | SA-028RB-24LP | 06941691924999 |
| SA-009RB-30RD | 06941691967132 | SA-115X-30   | 06941691926443 | SA-028RB-12LP | 06941691924982 |
| SA-015RB-30RD | 06941691968047 | SA-114-24    | 06941691926436 | SA-028RB-24LS | 06941691924975 |
| SA-018-24TS   | 06941691968092 | SA-113-24    | 06941691926429 | SA-028RB-12LS | 06941691924968 |
| SA-024M-24RD  | 06941691967125 | SA-112-24    | 06941691926412 | SA-028RB-24   | 06941691924951 |
| SA-026X-30XC  | 06941691968115 | SA-111X-24XC | 06941691926405 | SA-028M-24ML  | 06941691924944 |
| SA-045RB-30   | 06941691967071 | SA-111X-30   | 06941691926399 | SA-028M-24LP  | 06941691924937 |
| SA-005RB-24LS | 06941691966944 | SA-111-24    | 06941691926382 | SA-028M-12LP  | 06941691924920 |
| SA-157-24     | 06941691966890 | SA-110X-24XC | 06941691926375 | SA-028M-24LS  | 06941691924913 |
| SA-009RB-36ML | 06941691966876 | SA-110X-30   | 06941691926368 | SA-028M-12LS  | 06941691924906 |
| SA-053X-30XN  | 06941691966609 | SA-109X-24XC | 06941691926351 | SA-028M-24    | 06941691924890 |
| SA-053RB-30LS | 06941691966586 | SA-109X-30   | 06941691926344 | SA-028X-24XC  | 06941691924883 |
| SA-009RB-36LS | 06941691965817 | SA-108X-24XC | 06941691926337 | SA-028X-30    | 06941691924876 |
| SA-008RB-36LS | 06941691965800 | SA-108X-30   | 06941691926320 | SA-028X-12    | 06941691924869 |
| SA-015X-60    | 06941691965794 | SA-107X-12   | 06941691926313 | SA-028-24     | 06941691924852 |
| SA-074D-24    | 06941691965718 | SA-106X-12XC | 06941691926306 | SA-028-12     | 06941691924845 |
| SA-026RB-30LS | 06941691965695 | SA-106X-12   | 06941691926290 | SA-027-24     | 06941691924838 |
| SA-015RB-70LS | 06941691965664 | SA-106-12    | 06941691926283 | SA-026-03NV   | 06941691924821 |
| SA-104-24     | 06941691965657 | SA-105X-24XC | 06941691926276 | SA-026RB-24ML | 06941691924814 |

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| SA-009RB-15RD  | 06941691965640 | SA-105X-30   | 06941691926269 | SA-026RB-24LP | 06941691924807 |
| SA-053RB-120LS | 06941691965633 | SA-103-24    | 06941691926252 | SA-026RB-24LS | 06941691924791 |
| SA-053X-24XN   | 06941691965206 | SA-101-24    | 06941691926245 | SA-026RB-24   | 06941691924784 |
| SA-024M-12LS   | 06941691965008 | SA-100-24    | 06941691926238 | SA-026M-24ML  | 06941691924777 |
| SA-162RB-36RD  | 06941691965190 | SA-098-24    | 06941691926221 | SA-026M-24LP  | 06941691924760 |
| SA-162RB-24RD  | 06941691965183 | SA-097X-24XC | 06941691926214 | SA-026M-24LS  | 06941691924753 |
| SA-162RB-15RD  | 06941691965176 | SA-097X-30   | 06941691926207 | SA-026M-24    | 06941691924746 |
| SA-162RB-045RD | 06941691965169 | SA-096-24    | 06941691926191 | SA-026X-24XC  | 06941691924739 |
| SA-162RB-30LS  | 06941691965152 | SA-095-24    | 06941691926184 | SA-026X-30    | 06941691924722 |
| SA-162RB-12LS  | 06941691965145 | SA-094M-24ML | 06941691926177 | SA-026-24     | 06941691924715 |
| SA-162RB-03LS  | 06941691965138 | SA-094M-24LP | 06941691926160 | SA-025-03NV   | 06941691924708 |
| SA-026-30      | 06941691964247 | SA-094M-24LS | 06941691926153 | SA-025-24     | 06941691924692 |
| SA-053-30      | 06941691963318 | SA-094M-24   | 06941691926146 | SA-024RB-24ML | 06941691924685 |
| SA-009RB-12    | 06941691963011 | SA-094X-24XC | 06941691926139 | SA-024RB-24LP | 06941691924678 |
| SA-005RB-03    | 06941691963004 | SA-094X-30   | 06941691926122 | SA-024RB-24LS | 06941691924661 |
| SA-024-60NE    | 06941691962694 | SA-093-24    | 06941691926115 | SA-024RB-24   | 06941691924654 |
| SA-015RB-30    | 06941691962656 | SA-092-24    | 06941691926108 | SA-024M-24ML  | 06941691924647 |
| SA-045RB-24    | 06941691962632 | SA-091-24    | 06941691926092 | SA-024M-24LP  | 06941691924630 |
| SA-023-24ML    | 06941691962366 | SA-089-24    | 06941691926085 | SA-024M-24LS  | 06941691924623 |
| SA-023-24LS    | 06941691962359 | SA-088X-24XC | 06941691926078 | SA-024M-24    | 06941691924616 |
| SA-009RB-36LP  | 06941691962328 | SA-088X-30   | 06941691926061 | SA-024X-24XC  | 06941691924609 |
| SA-009RB-12LP  | 06941691962311 | SA-088-24    | 06941691926054 | SA-024X-30    | 06941691924593 |

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| SA-008RB-12LP | 06941691962298 | SA-087-24     | 06941691926047 | SA-024-24NE   | 06941691924586 |
| SA-008RB-40ML | 06941691962281 | SA-086-24     | 06941691926030 | SA-024-12NE   | 06941691924579 |
| SA-008RB-12ML | 06941691962274 | SA-085-24BN   | 06941691926023 | SA-024-24     | 06941691924562 |
| SA-008RB-03ML | 06941691962267 | SA-085-24     | 06941691926016 | SA-023-24NE   | 06941691924555 |
| SA-006M-03ML  | 06941691962250 | SA-084-24     | 06941691926009 | SA-023-24     | 06941691924548 |
| SA-006M-03LS  | 06941691962243 | SA-083-24     | 06941691925996 | SA-022-24     | 06941691924531 |
| SA-006M-12LP  | 06941691962236 | SA-082-24     | 06941691925989 | SA-021X-24XC  | 06941691924524 |
| SA-005M-40LP  | 06941691962229 | SA-081-24     | 06941691925972 | SA-021X-24XN  | 06941691924517 |
| SA-005M-03LP  | 06941691962212 | SA-080-24     | 06941691925965 | SA-021X-30    | 06941691924500 |
| SA-005M-03ML  | 06941691962205 | SA-078RB-24ML | 06941691925958 | SA-021-24     | 06941691924494 |
| SA-015RB-36LP | 06941691962199 | SA-078RB-24LP | 06941691925941 | SA-017-24OT   | 06941691924487 |
| SA-036-45     | 06941691962182 | SA-078RB-24LS | 06941691925934 | SA-017-24TS   | 06941691924470 |
| SA-015-30     | 06941691960249 | SA-078RB-24   | 06941691925927 | SA-016-24OT   | 06941691924463 |
| SA-002-30     | 06941691960003 | SA-078M-24ML  | 06941691925910 | SA-016-24TS   | 06941691924456 |
| SA-024X-24XN  | 06941691959878 | SA-078M-24LP  | 06941691925903 | SA-015RB-24ML | 06941691924449 |
| SA-053RB-77LS | 06941691959748 | SA-078M-24LS  | 06941691925897 | SA-015RB-24LP | 06941691924432 |
| SA-040-24     | 06941691959663 | SA-078M-24    | 06941691925880 | SA-015RB-24LS | 06941691924425 |
| SA-015RB-24   | 06941691959366 | SA-078-24     | 06941691925873 | SA-015M-24ML  | 06941691924418 |
| SA-015RB-30LS | 06941691959359 | SA-077-24     | 06941691925866 | SA-015M-24LP  | 06941691924401 |
| SA-015RB-12LS | 06941691959175 | SA-076-24     | 06941691925859 | SA-015M-24LS  | 06941691924395 |
| SA-009RB-40LS | 06941691959168 | SA-075-24     | 06941691925842 | SA-015M-24    | 06941691924388 |
| SA-008RB-36LP | 06941691959151 | SA-072X-24XC  | 06941691925835 | SA-015X-24XC  | 06941691924371 |

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| TS-DSA-PS15    | 06941691958987 | SA-072X-30   | 06941691925828 | SA-015X-30    | 06941691924364 |
| SA-003X(NF)-30 | 06941691958840 | SA-071X-24XC | 06941691925811 | SA-015-24     | 06941691924357 |
| SA-001X-30     | 06941691957997 | SA-071X-30   | 06941691925804 | SA-014-24OT   | 06941691924340 |
| SA-044-15      | 06941691957959 | SA-071-24    | 06941691925798 | SA-014-24TS   | 06941691924333 |
| SA-008RB-12LS  | 06941691957843 | SA-070X-24XC | 06941691925781 | SA-014-24NE   | 06941691924326 |
| SA-008RB-40LS  | 06941691957775 | SA-070X-30   | 06941691925774 | SA-014-24     | 06941691924319 |
| SA-006M-12LS   | 06941691957768 | SA-069X-24XC | 06941691925767 | SA-011-24OT   | 06941691924302 |
| SA-159-24      | 06941691957751 | SA-069X-30   | 06941691925750 | SA-011-12OT   | 06941691924296 |
| SA-008RB-30LS  | 06941691955467 | SA-068-24    | 06941691925743 | SA-011-24TS   | 06941691924289 |
| SA-008RB-03LS  | 06941691955443 | SA-066-24    | 06941691925736 | SA-011-24     | 06941691924272 |
| SA-045RB-24LP  | 06941691955160 | SA-062X-24XC | 06941691925729 | SA-009RB-24ML | 06941691924265 |
| SA-008M-12LP   | 06941691955115 | SA-062X-30   | 06941691925712 | SA-009RB-24LP | 06941691924258 |
| SA-008M-03LS   | 06941691955108 | SA-062-24    | 06941691925705 | SA-009RB-24LS | 06941691924241 |
| SA-008M-30LS   | 06941691955092 | SA-061-24    | 06941691925699 | SA-009RB-24   | 06941691924234 |
| SA-008M-12LS   | 06941691955085 | SA-060-24    | 06941691925682 | SA-008RB-24ML | 06941691924227 |
| SA-001X-12XN   | 06941691954538 | SA-059-24    | 06941691925675 | SA-008RB-24LP | 06941691924210 |
| SA-005M-24LS   | 06941691954057 | SA-057X-24XC | 06941691925668 | SA-008RB-24LS | 06941691924203 |
| SA-001X-24XN   | 06941691954040 | SA-004-30    | 06941691924111 | SA-008RB-24   | 06941691924197 |
| SA-024M-30LS   | 06941691947004 | SA-003X-24XC | 06941691924104 | SA-008M-24ML  | 06941691924180 |
| SA-059-35      | 06941691946991 | SA-003X-30   | 06941691924098 | SA-008M-24LP  | 06941691924173 |
| SA-015M-12LS   | 06941691946984 | SA-002-24    | 06941691924081 | SA-008M-24LS  | 06941691924166 |
| SA-005M-12LS   | 06941691946977 | SA-001X-24XC | 06941691924074 | SA-008M-24    | 06941691924159 |

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| SA-024-30NE | 06941691946960 | SA-001X-03XC  | 06941691924067 | SA-007RB-03   | 06941691924142 |
| SA-003X-12  | 06941691946953 | SA-001X-24    | 06941691924050 | SA-006M-03    | 06941691924135 |
| SA-014-12   | 06941691946946 | SA-001X-12    | 06941691924043 | SA-005M-03    | 06941691924128 |
| SA-001-12   | 06941691924029 | SA-001-24     | 06941691924036 | SA-015X-24    | 06941691982265 |
| SA-124X-24  | 06941691982272 | SA-130RB-16ML | 06941691908050 | SA-048X-30    | 06941691911845 |
| SA-172-24   | 06941691914822 | SA-001-30LS   | 06941691918141 | SA-053-40     | 06941691917939 |
| SA-001-30LS | 06941691918141 | SA-125RB-24RD | 06941691977704 | SA-005RB-12RD | 06941691977728 |