

EU DECLARATION OF CONFORMITY

Document No. : DOC-009-01

Rev: B3

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 : Fitting/Adapters

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH20QT

UMDNS Code : 11726

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+A1:2025

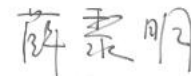
Directive 2011/65/EU Annex II (EU) 2015/863

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

CE mark : 

Place, Date of Issue :

Signature :



Shenzhen, Sep. 28th, 2025

Position: General Manager

Annex I List Of Fitting/Adapters

| Model | UDI-DI | Model | UDI-DI | Model | UDI-DI |
|-----------|----------------|--------------|----------------|-------------|----------------|
| BPC01P-45 | 06941691981404 | EKA-B-G-I-10 | 06941691914235 | EKA-UA-10-A | 06941691946755 |
| BPC38-45 | 06941691980827 | EKA-N-G-A-10 | 06941691969884 | EKA-US-10-I | 06941691946380 |
| BPC42 | 06941691978725 | EKA-B-S-A-10 | 06941691969877 | EKA-US-10-A | 06941691946373 |
| BPC39 | 06941691978718 | EKA-N-G-I-10 | 06941691914891 | EKA-UG-14-I | 06941691946366 |
| BPC37 | 06941691978664 | EKA-UBG-10-I | 06941691964728 | EKA-UG-14-A | 06941691946359 |
| BPC28 | 06941691978701 | EKA-UBG-10-A | 06941691964711 | EKA-UB-10-I | 06941691946342 |
| BPC26 | 06941691978695 | EKA-BG-3-A | 06941691964056 | EKA-UB-10-A | 06941691946335 |
| BPC25 | 06941691978688 | EKA-UW-10-I | 06941691963592 | EKA-UG-10-I | 06941691946328 |
| BPC24 | 06941691978671 | EKA-UW-10-A | 06941691963585 | EKA-UG-10-A | 06941691946311 |
| BPC10-D | 06941691978954 | EKA-US-14-I | 06941691961680 | EKA-NW-10 | 06941691946304 |
| BPC10 | 06941691975205 | EKA-US-14-A | 06941691961673 | EKA-BW-10 | 06941691946298 |
| BPC11 | 06941691975212 | EKA-US-12-I | 06941691961666 | EKA-NA-10 | 06941691946281 |
| BPC38 | 06941691975229 | EKA-US-12-A | 06941691961659 | EKA-BA-10 | 06941691946274 |
| BPC12 | 06941691973782 | EKA-UG-12-I | 06941691961642 | EKA-NF-10 | 06941691946267 |
| BPC48 | 06941691973799 | EKA-UG-12-A | 06941691961635 | EKA-BF-10 | 06941691946250 |
| CTA-S05 | 06941691979364 | EKA-UB-12-I | 06941691961628 | EKA-NS-10 | 06941691946243 |
| CTA-M04 | 06941691959809 | EKA-UB-12-A | 06941691961611 | EKA-BS-10 | 06941691946236 |
| CTA-M03 | 06941691959793 | EKA-VC-10 | 06941691955450 | EKA-NG-10 | 06941691946229 |
| CTA-S04 | 06941691954200 | EKA-UB-14-I | 06941691954033 | EKA-BG-10 | 06941691946212 |
| CTA-S03 | 06941691954194 | EKA-UB-14-A | 06941691954026 | EKA-N-S-10 | 06941691946205 |

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| CTA-S02 | 06941691954187 | EKA-UW-14-I | 06941691946793 | EKA-B-S-10 | 06941691946182 |
| CTA-S01 | 06941691954170 | EKA-UW-14-A | 06941691946786 | EKA-B-G-10 | 06941691946175 |
| CTA-M02 | 06941691954163 | EKA-BW-14 | 06941691946779 | EKA-N-S-I-10 | 06941691913832 |
| CTA-M01 | 06941691954156 | EKA-UA-10-I | 06941691946762 | EKA-B-G-A-10 | 06941691913948 |
| TNC-PH-ST001 | 06941691980643 | ELA-PH5-D5-I | 06941691980360 | ELA-TMX5PH-PH5-A | 06941691979449 |
| EKA-B-S-I-10 | 06941691912798 | ELA-PH5-D5-A | 06941691980315 | ELA-TMX5PH-MQ5-I | 06941691979494 |
| CA-PH-RP-03 | 06941691966852 | ELA-NKA5-D5-I | 06941691980391 | ELA-TMX5PH-MQ5-A | 06941691979487 |
| EKA-N-S-A-10 | 06941691913733 | ELA-NKA5-D5-A | 06941691980346 | ELA-TMX5PH-CV5-I | 06941691979531 |
| ELAB-TMX5NE-PH5-A | 06941691979692 | ELA-MR5-D5-I | 06941691980384 | ELA-TMX5PH-CV5-A | 06941691979524 |
| ELAB-TMX5NE-PH5 | 06941691979685 | ELA-MR5-D5-A | 06941691980339 | ELA-TMX5-PH5-I | 06941691979395 |
| ELAB-TMX5PH-PH5-I | 06941691979593 | ELA-MQ5-D5-I | 06941691980353 | ELA-TMX5-PH5-A | 06941691979388 |
| ELAB-TMX5PH-PH5-A | 06941691979586 | ELA-MQ5-D5-A | 06941691980308 | ELA-TMX5NE-PH5-I | 06941691979470 |
| ELAB-TMX5-PH5-I | 06941691979579 | ELA-DG5-D5-I | 06941691980377 | ELA-TMX5NE-PH5-A | 06941691979463 |
| ELAB-TMX5-PH5-A | 06941691979562 | ELA-DG5-D5-A | 06941691980322 | ELA-TMX5NE-MQ5-I | 06941691979517 |
| ELAB-TMX5PH-PH5 | 06941691967170 | ELA-TMX5PH-PH5-I | 06941691979456 | ELA-TMX5NE-MQ5-A | 06941691979500 |
| ELAB-TMX5-PH5 | 06941691966913 | ELA-SL5-NKA5 | 06941691966494 | ELA-TMX5NE-CV5-I | 06941691979555 |
| ELA-TMX5NE-CV5-A | 06941691979548 | ELA-SL5-SM5 | 06941691966487 | ELA-TMX5PH-MQ5 | 06941691954750 |
| ELA-TMX5-MQ5-I | 06941691979418 | ELA-NKA5-SM5 | 06941691966470 | ELA-TMX5NE-PH5 | 06941691954743 |
| ELA-TMX5-MQ5-A | 06941691979401 | ELA-NKA5-PH5 | 06941691966463 | ELA-TPH5-CV5 | 06941691954521 |
| ELA-TMX5-CV5-I | 06941691979432 | ELA-MQ5-SM5 | 06941691966456 | ELA-TMX5PH-PH5 | 06941691942580 |
| ELA-TMX5-CV5-A | 06941691979425 | ELA-MQ5-SL5 | 06941691966449 | ELA-TMX5-CV5 | 06941691942573 |
| ELA-DG5-D5 | 06941691975724 | ELA-MQ5-PH5 | 06941691966432 | ELA-TMX5-MQ5 | 06941691942566 |

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| ELA-PH5-D5 | 06941691946199 | ELA-MQ5-NKA5 | 06941691966425 | ELA-TMX5-PH5 | 06941691942559 |
| ELA-SM5-SL5 | 06941691966531 | ELA-NKA5-SL5 | 06941691966418 | TNC-NC010 | 06941691979050 |
| ELA-SM5-PH5 | 06941691966524 | ELA-MQ5-CV5 | 06941691960577 | TNC-NC009 | 06941691979043 |
| ELA-SM5-NKA5 | 06941691966517 | ELA-TMX5NE-CV5 | 06941691954781 | TNC-NC008 | 06941691979036 |
| ELA-SL5-PH5 | 06941691966500 | ELA-TMX5PH-CV5 | 06941691954774 | TNC-NC007 | 06941691979029 |
| TNC-CO2-SY02 | 06941691982258 | ELA-TMX5NE-MQ5 | 06941691954767 | TNC-NC006 | 06941691979012 |
| TNC-RP-AA001 | 06941691969327 | TNC-NC044 | 06941691979265 | TNC-NC005 | 06941691979005 |
| TNC-SL016 | 06941691980254 | TNC-NC043 | 06941691979258 | TNC-NC004 | 06941691978992 |
| TNC-PH-P001 | 06941691980438 | TNC-NC042 | 06941691979241 | TNC-AA003 | 06941691979357 |
| TNC-ETCO2-MR-001 | 06941691980575 | TNC-NC040 | 06941691979234 | TNC-RP-DA002 | 06941691969334 |
| TNC-AA002 | 06941691980247 | TNC-NC030 | 06941691979197 | TNC-NC046 | 06941691979289 |
| TNC-SL048 | 06941691979302 | TNC-NC029 | 06941691979180 | TNC-NC045 | 06941691979272 |
| TNC-SL037 | 06941691979227 | TNC-NC028 | 06941691979173 | TNC-NC013 | 06941691979081 |
| TNC-SL032 | 06941691979210 | TNC-NC027 | 06941691979166 | TNC-NC012 | 06941691979074 |
| TNC-SL031 | 06941691979203 | TNC-NC026 | 06941691979159 | TNC-NC011 | 06941691979067 |
| TNC-SL017 | 06941691977483 | TNC-NC025 | 06941691979142 | TNC-NC049 | 06941691979319 |
| TNC-SL015 | 06941691979098 | TNC-NC024 | 06941691979135 | TNC-NC047 | 06941691979296 |
| TNC-SL014 | 06941691977476 | TNC-NC022 | 06941691979128 | TNC-NC050 | 06941691979326 |
| TNC-NC052 | 06941691979340 | TNC-NC021 | 06941691979111 | TNC-NC020 | 06941691979104 |
| TNC-NC051 | 06941691979333 | TNC-NC033 | 06941691982548 | TNC-NC034 | 06941691982555 |
| TNC-NC035 | 06941691982562 | TNC-NC036 | 06941691982579 | TNC-SL039 | 06941691977469 |

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| ELAG-TMX5NE-PH5-A | 06941691980223 | TNC-CO2-SY03 | 06941691911739 | EKA-SEA-A | 06941691978732 |
| EKA-SEP | 06941691946168 | EKA-LCA-GR4 | 06941691964841 | EKA-LCP-I | 06941691946144 |
| EKA-SEA | 06941691946151 | EKA-LCP-A | 06941691946137 | EKA-LCA-I | 06941691946120 |
| EKA-LCA-A | 06941691946113 | EKA-LCN-I | 06941691907886 | EKA-LCA | 06941691984344 |
| CA-RP-PS-03 | 06941691986034 | TNC-SL060 | 06941691986515 | TNC-SL061 | 06941691986522 |
| TNC-SL062 | 06941691986539 | TNC-SL063 | 06941691986546 | | |