# CE DECLARATION OF CONFORMITY according to European medical device regulation 2017/745

## DECLARATION CE DE CONFORMITE selon le règlement européen 2017/745

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| MANUFACTURER<br>FABRICANT | **BioSerenity**<br>ICM-iPEPS<br>47, Boulevard de l'Hôpital<br>75013 Paris<br>France |
| SRN NUMBER<br>NUMERO SRN | FR-MF-000000497 |
| PRODUCT DESIGNATION<br>DÉSIGNATION DU PRODUIT | Medical mask CIDALTEX®<br>Masque médical CIDALTEX® |
| PRODUCT REFERENCE<br>REFERENCE PRODUIT | 1016-07013-FR<br>1016-07013-US<br>1016-07017-FR<br>1016-07017-US |
| INTENDED USE<br>INDICATION D'UTILISATION | The Medical mask CIDALTEX is intended to avoid, during exhalation of the one who wears the mask, the projection of secretions form upper airways and saliva that may contain infectious agents transmissible by aerosols or airborne.<br><br>Le masque médical CIDALTEX est destiné à éviter, lors de l'expiration de celui qui le porte, la projection de secrétions des voies aériennes supérieures ou de salive pouvant contenir des agents infectieux transmissibles par voie « gouttelettes » ou « aérienne ». |
| EMDN CODE<br>CODE EMDN | T020604 |
| CLASSIFICATION | I rule 1<br>I règle 1 |

We hereby declare that the above-mentioned products meet the requirements of the European medical device regulation 2017/745. All supporting documentation is retained at the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of BioSerenity.
Nous certifions que les produits mentionnés ci-dessus sont conformes au règlement 2017/745/CEE. Les preuves de conformité sont maintenues dans les locaux du fabricant. Cette déclaration de conformité est délivrée sous la seule responsabilité de BioSerenity.

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| PLACE<br>A | Paris |
| DATE OF ISSUE<br>DATE | July 30th 2021<br>30 juillet 2021 |
| SIGNATURE |  |
| NAME / NOM<br>POSITION / TITRE | Julien DUPONT<br>Quality and Regulatory Affairs Director<br>Directeur Qualité et Affaires Réglementaires |

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**REFERENCE OF APPLIED** **REGULATORY STANDARDS**

## REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES

| Standard number<br>Numéro du standard | Standard title<br>Titre du standard |
|---|---|
| EN 14683:2019+AC:2019 | Medical face masks - Requirements and test methods |
| EN ISO 14971: 2019 | Medical devices — Application of risk management to medical devices |
| EN ISO 10993-1:2018 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| EN ISO 10993-2 : 2006 | Biological evaluation of medical devices — Part 2: Animal Welfare Requirements |
| ISO 10993-5 :2009 | Biological evaluation of medical devices – Part 5: tests for in vitro cytotoxicity |
| ISO 10993-10 :2013 | Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization |
| EN ISO 10993-12 : 2012 | Biological evaluation of medical devices — Part 12: Sample preparation and reference materials |
| NF EN ISO 10993-17: 2009 | Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances |
| ISO 10093-18: 2020 | Biological evaluation of medical devices — Part 18: Chemical characterization of materials |
| ISO/TS 10993-19: 2006 | Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials |
| EN ISO 13485: 2016/AC:2018 | Medical devices - Quality management systems - Requirements for regulatory purposes |
| EN ISO 13485: 2016 | Medical devices - Quality management systems - Requirements for regulatory purposes |
| EN ISO 15223-1: 2016 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements |

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| Applied regulatory requirements | European Medical Device Regulation (2017/745) |

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## REFERENCE OF APPLIED COMMON SPECIFICATIONS
## REFERENCE DES SPECIFICATIONS COMMUNES APPLIQUÉES

No common specification applicable