



EU DECLARATION OF CONFORMITY according to European medical device regulation 2017/745
DECLARATION EU DE CONFORMITE selon le règlement européen 2017/745

MANUFACTURER
FABRICANT

BioSerenity
ICM-iPEPS
47, Boulevard de l'Hôpital
75013 Paris
France

SRN NUMBER
NUMERO SRN

FR-MF-000000497

PRODUCT DESIGNATION
DÉSIGNATION DU PRODUIT

CIDALTEX® Surgical IIR mask
Masque Chirurgical IIR CIDALTEX®

PRODUCT REFERENCE
REFERENCE PRODUIT

1016-07012-FR
1016-07012-US

BASIC UDI-DI NUMBER
NUMERO IUD-ID de Base

361522CidaltexSurgVOUR

INTENDED USE
INDICATION D'UTILISATION

The CIDALTEX® Surgical Mask is intended to avoid, during exhalation of the one who wears the mask, the projection of airway secretions and saliva able to contain infectious agents transmissible by aerosols or airborne and to be used in a medical environment in order to protect against transfer of microorganisms, body fluids, and airborne particulates especially (by inactivation of the microorganism).

Le masque chirurgical CIDALTEX® BioSerenity est destiné à éviter, lors de l'expiration de celui qui le porte, la projection de sécrétions des voies aériennes supérieures ou de salive pouvant contenir des agents infectieux transmissibles par voie « gouttelettes » ou « aérienne »

EMDN CODE
CODE EMDN

T020604

CLASSIFICATION

I rule 1
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.

PLACE
A

Paris

DATE OF ISSUE
DATE

February 10th 2022
10 février 2022

SIGNATURE

NAME/ NOM
POSITION/ TITRE

MélanieRENAUD SAMIRI
Quality and Regulatory Affairs Director/ Directeur Qualité et Affaires Réglementaires



REFERENCE OF APPLIED REGULATORY STANDARDS
REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES

Standard number Numéro du standard	Standard title 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 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
ISO 20417 :2021	Medical devices – Information to be supplied by the manufacturer

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