



EU DECLARATION OF CONFORMITY according to European medical device regulation 2017/745
DECLARATION UE 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	Masque Cidaltex® Spécial Endoscopie
PRODUCT REFERENCE REFERENCE PRODUIT	1016-07014-FR
BASIC UDI-DI NUMBER NUMERO IUD-ID de Base	361522CidaltexEndoVOJU
INTENDED USE INDICATION D'UTILISATION	<p>The Endomasks are intended for use during transnasal endoscopy or rigid endoscopy, to protect the healthcare professionals against possible projections by the patient of secretions from upper airways and saliva that may contain infectious agents transmissible by aerosols or airborne.</p> <p>Les masques CIDALTEX Spécial Endoscopie sont destinées à être utilisés pendant une fibroscopie transnasale ou une endoscopie rigide, pour protéger le praticien contre de possible projections par le patient de sécrétions des voies aériennes supérieures ou de la salive pouvant contenir des agents infectieux transmissibles par voie « aérienne » ou par « gouttelettes ».</p>
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 7 th 2022 7 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 10993-18: 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
ISO 20417 :2021	Medical devices – Information to be supplied by the manufacturer
EN 62366:2008	Medical devices - Application of usability engineering to medical devices

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



REFERENCE OF APPLIED COMMON SPECIFICATIONS
REFERENCE DES SPECIFICATIONS COMMUNES APPLIQUÉES

NF EN 149+A1 Septembre 2009: Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking - Appareils de protection respiratoire