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 chirurgical type IIR Masque chirurgical type IIR – BNP Surgical Face Mask - Type IIR Surgical Face Mask - Type IIR – BNP Masque chirurgicale enfant - Type IIR Surgical Face Mask KID - Type IIR Masque chirurgical type IIR – Elastique plat Surgical Face Mask - Type IIR - Flat Elastic
PRODUCT REFERENCE REFERENCE PRODUIT	1016-07007-EU 1016-07008-EU 1016-07009-FR 1016-07016-FR
BASIC UDI-DI NUMBER NUMERO IUD-ID de Base	361522SurgMaskV0LM
NTENDED USE INDICATION D'UTILISATION	The Bioserenity Surgical Face Mask type IIR 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. It also allows the wearer of the mask to protect themselves from liquid projections and avoid contamination. Le masque chirurgical type IIR Bioserenity est destiné à éviter, lors de l'expiration de celui qui le porte, la projection de secrétions des voies aériennes supérieures ou salive pouvant contenir des agents infectieux transmissibles par voie « gouttelettes » ou « aérienne ». Il permet également au porteur du masque de se protéger des projections liquides et éviter les contaminations.
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 7th 2022 7 février 2022
SIGNATURE	
NAME / NOM POSITION / TITRE	Mélanie RENAUD SAMIRI Quality and Regulatory Affairs Director/ Directeur Qualité et Affaires Réglementaires

BIOSERENITY

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 10993-5:2009	Biological evaluation of medical devices – Part 5: tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization
ISO 10993-13:2010	Biological evaluation of medical devices – Part 13:Identification and quantification of degradation product from polymeric medical devices
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes: §4.1.1, 4.2.1, 4.2.4, 4.2.5,7.5.1
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
EN ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
ISO 20417 :2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice
EN ISO 14971:2019	Medical devices — Application of risk management to medical devices

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

BIOSERENITY

REFERENCE OF APPLIED COMMON SPECIFICATIONS
REFERENCE DES SPECIFICATIONS COMMUNES APPLIQUÉES

No common specification applicable