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

DECLARATION CE 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 • Masque chirurgical enfant - Type IIR • Masque chirurgical type IIR – Elastique plat • Masque chirurgical type II • Masque chirurgical enfant - Type II • Masque chirurgical type II – Elastique plat • Surgical Face Mask - Type IIR • Surgical Face Mask - Type IIR – BNP • Surgical Face Mask KID - Type IIR • Surgical Face Mask - Type IIR - Flat Elastic • Surgical Face Mask - Type II • Surgical Face Mask KID - Type II • Surgical Face Mask - Type II - Flat Elastic
PRODUCT REFERENCE REFERENCE PRODUIT	1016-07007-EU 1016-07008-EU 1016-07009-FR 1016-07016-FR 1016-07001-EU 1016-07019-EU 1016-07020-EU
BASIC UDI-DI Number Numéro IUD-ID de base	361522SurgMaskV0LM
INTENDED USE INDICATION D'UTILISATION	The Bioserenity Surgical Face Masks type II and IIR are 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. The type IIR mask also allows the wearer of the mask to protect themselves from liquid projections and avoid contamination. Les masques chirurgicaux type II et IIR Bioserenity sont destinés 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 ». Le masque IIR 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	March 23th, 2023 / 23 Mars 2023
SIGNATURE	
NAME / NOM POSITION / TITRE	Mélanie RENAUD 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 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
ISO 10993-13:2010	Biological evaluation of medical devices – Part 13:Identification and quantification of degradation product from polymeric medical devices
ISO 10993-18/A1:2022	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 13485:2016/A11:2021	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 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN 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/A11:2021	Medical devices — Application of risk management to medical devices

Applied Regulation **Règlement appliqué**	**Regulation title** **Titre du réglement**
REG (UE) 2017/745	**REGULATION (EU) 2017/745** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
Rect REG (UE) 2017/745	C**orrigendum to Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
Rect REG (UE) 2017/745 (2)	**Corrigendum to Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
REG (UE) 2020/561	REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions
DÉCISION (UE) 2020/437	COMMISSION IMPLEMENTING DECISION (EU) 2020/437 of 24 March 2020 on **the harmonised standards** for medical devices drafted in support of Council Directive 93/42/EEC
DECISION (EU) 2021/1182	COMMISSION IMPLEMENTING DECISION (EU) 2021/1182 of 16 July 2021 on the **harmonised standards** for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council
DECISION (EU) 2022/6	COMMISSION IMPLEMENTING DECISION (EU) 2022/6 of 4 January 2022 amending Implementing Decision (EU) 2021/1182 as regards **harmonised standards** for biological evaluation of medical devices, sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer, processing of health care products and home light therapy equipment
DECISION (EU) 2022/757	Commission Implementing Decision (EU) 2022/757 of 11 May 2022 amending Implementing Decision (EU) 2021/1182 as regards **harmonised standards** for quality management systems, sterilisation and application of risk management to medical devices
REC 2013/172/UE	COMMISSION RECOMMENDATION of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union

REFERENCE OF APPLIED COMMON SPECIFICATIONS
REFERENCE DES SPECIFICATIONS COMMUNES APPLIQUÉES

No common specification applicable