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CE DECLARATION OF CONFORMITY according to Directive 93/42/EEC amended by Directive 2007/47/EC

DECLARATION CE DE CONFORMITE selon la Directive 93/42/CEE amendée par la Directive 2007/47/CE

MANUFACTURER FABRICANT	BioSerenity ICM-iPEPS 47, Boulevard de l'Hôpital 75013 Paris France
DESIGNATION PRODUCT REFERENCE REFERENCE PRODUIT	**Bioserenity Cloud V 3.7.0** 1012-21001-UN
UDI NUMBER NUMERO IUD	0361522000286
GMDN CODE CODE GMDN	46564
CLASSIFICATION	IIa rule 10 IIa règle 10
CONFORMITY ASSESSMENT ROUTE EVALUATION DE LA CONFORMITE	Annex II - Full quality assurance system excl. Section 4 Annexe II - Système complet d'assurance qualité excl. Section 4

We hereby declare that the above-mentioned products meet the transposition into national law provisions of council Directive 93/42/EEC for medical devices as amended by Directive 2007/47/EC. All supporting documentation is retained at the premises of the manufacturer.
Nous certifions que les produits mentionnés ci-dessus sont conformes à la Directive européenne 93/42/CEE transposée en droit national relative aux dispositifs médicaux amendée par la Directive 2007/47/CE. Les preuves de conformité sont maintenues dans les locaux du fabricant.

NOTIFIED BODY ORGANISME NOTIFIE	BSI 2797 - EC certificate n° CE 672474 BSI 2797 - Certificat CE n° CE 672474
PLACE A	Paris
DATE OF ISSUE DATE	January 7th, 2022 7 janvier 2022
SIGNATURE	
NAME NOM	Mélanie RENAUD-SAMIRI
POSITION TITRE	Quality and Regulatory Affairs Director Directeur Qualité et Affaires Réglementaires

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REFERENCE OF APPLIED REGULATORY STANDARDS
REFERENCE DES NORMES RÉGLEMENTAIRES APPLIQUÉES

Standard number Numéro du standard	Standard title Titre du standard
EN 20417: 2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 13485:2016/AC:2018	Medical devices — Quality management sys¬tems — Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice (ISO 14155:2011)
EN ISO 14971:2019	Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
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 (ISO 15223-1:2016, Corrected version 2017-03)
ISO 20417 :2021	Medical devices — Information to be supplied by the manufacturer
ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971
EN 60601-2-47:2015	Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
IEC 62304:2006/AMD 1:2015	Medical device software - Software life-cycle processes
EN 62366-1:2015+A1:2020	Medical devices - Application of usability engineering to medical devices
EN 62366-2:2016	Guidance on the application of usability engineering to medical devices

REFERENCE OF APPLIED REGULATORY TEXTS
REFERENCE DES TEXTES RÉGLEMENTAIRES APPLIQUÉES

Regulatory text reference **Référence du texte réglementaire**
COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
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
C1 REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
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
COMMISSION IMPLEMENTING DECISION (EU) 2021/610 of 14 April 2021 amending Implementing Decision (EU) 2020/437 as regards harmonised standards on medical vehicles and their equipment, anaesthetic and respiratory equipment, biological evaluation of medical devices, packaging for terminally sterilised medical devices, sterilisation of health care products, clinical investigation of medical devices for human subjects, non-active surgical implants, medical devices utilising animal tissues and their derivatives, electroacoustics and medical electrical equipment
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
COMMISSION RECOMMENDATION of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union
RGPD - REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
COMMISSION REGULATION (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices