BIOSERENITY

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	**Bioserenity Platform**
PRODUCT REFERENCE REFERENCE PRODUIT	1019-20001-EU
UDI NUMBER NUMERO IUD	03615220002887
GMDN CODE CODE GMDN	59378
CLASSIFICATION	I rule 12 I règle 12
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	Not applicable Non applicable
PLACE A	Paris
DATE OF ISSUE DATE	May 25, 2021 25 mai, 2021
SIGNATURE	
NAME NOM	Julien Dupont
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

Number	Standard Title
EN 1041:2008/A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485: 2016/AC:2018	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971: 2019	Medical devices — Application of risk management to medical devices
ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971
EN ISO 15223-1: 2017	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
IEC 62304+A1: 2018	Medical device software - Software life-cycle processes
IEC 62366-1: 2015/A1:2020	Medical devices - Application of usability engineering to medical devices

Applied regulatory requirements	European Medical Device Directive (93/42/CEE amended by 2007/47/EU)
	General Data Protection Regulation (2016/679)