

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 729450 R000

**Manufacturer:** BioSerenity

**Address:**

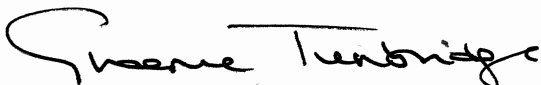
ICM-iPEPS  
47 Boulevard de l'Hôpital  
Paris  
75013  
France

**Single Registration Number:** FR-MF-000000497

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-12-12**

Current Issue Date: **2022-12-12**

Starting Validity Date: **2022-12-12**

Expiry Date: **2027-12-11**

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### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Active non-implantable devices for diagnosis and monitoring of vital and non-vital physiological parameters	Class IIa
Software for diagnosis and monitoring of vital and non-vital physiological parameters	Class IIa



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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference Number	Action
Current	3218516	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.