

# EU Quality Management System Certificate

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

## MDR 802592 R000

**Manufacturer:** BioSerenity Medical Devices Group

**Address:**

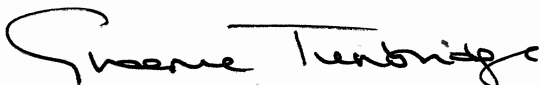
6/8 Rue Jean Antoine de Baïf  
Paris  
75013  
France

**Single Registration Number:** FR-MF-000039391

**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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional 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 Global Regulatory & Quality

First Issue Date: **2024-02-23**

Current Issue Date: **2025-03-20**

Starting Validity Date: **2025-03-20**

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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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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
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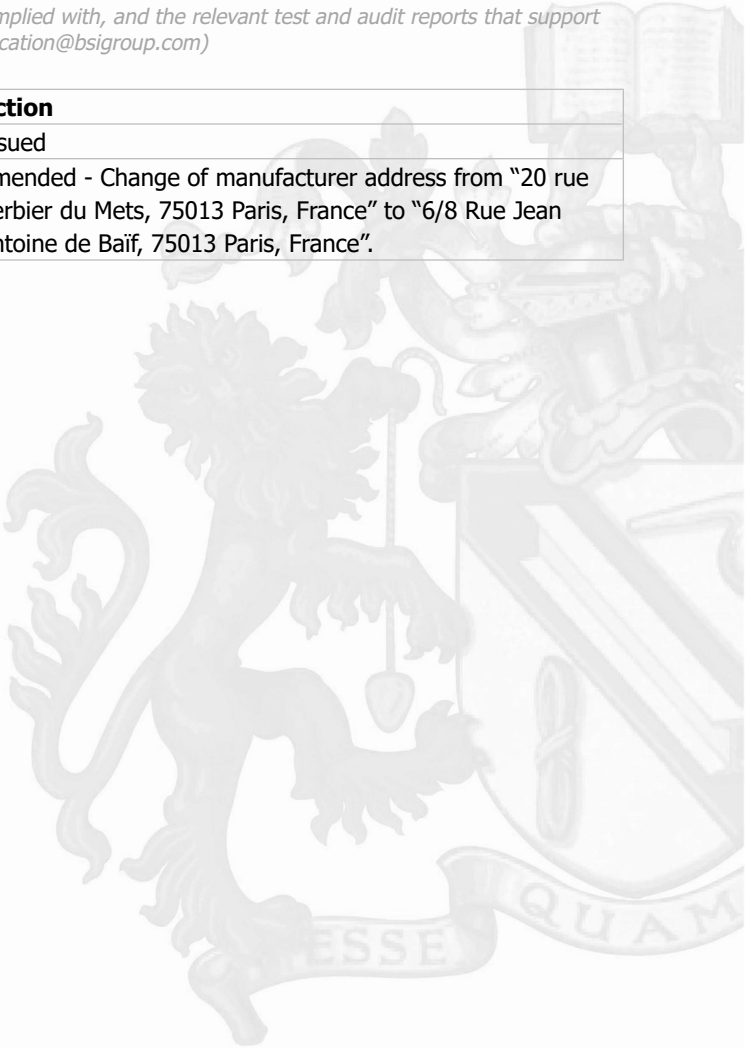
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**MDR 802592 R000**

**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](mailto:Certificate.Verification@bsigroup.com))*

Date	Reference Number	Action
2024-02-23	30078198	Issued
Current	30293053	Amended - Change of manufacturer address from "20 rue Berbier du Mets, 75013 Paris, France" to "6/8 Rue Jean Antoine de Baïf, 75013 Paris, France".



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