

# EU Quality Management System Certificate

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

## MDR 724463 R001

**Manufacturer:** Biotronics3D

**Address:**

10 Upper Berkeley Street  
London  
W1H 7PE  
United Kingdom

**Single Registration Number:** Not Available

**EU Authorised Representative:** Skyer Medical Imaging S.R.L.

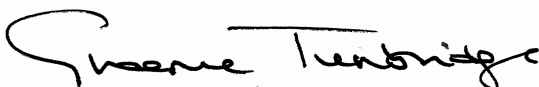
**Address:**

Str. Fabrica de Caramida nr. 1A, Casa 36  
Bucharest, 013471  
Romania

**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: **2020-09-17**

Current Issue Date: **2025-08-11**

Starting Validity Date: **2025-09-17**

Expiry Date: **2030-09-16**

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

Device(s)	Risk Classification
3Dnet	Class IIa



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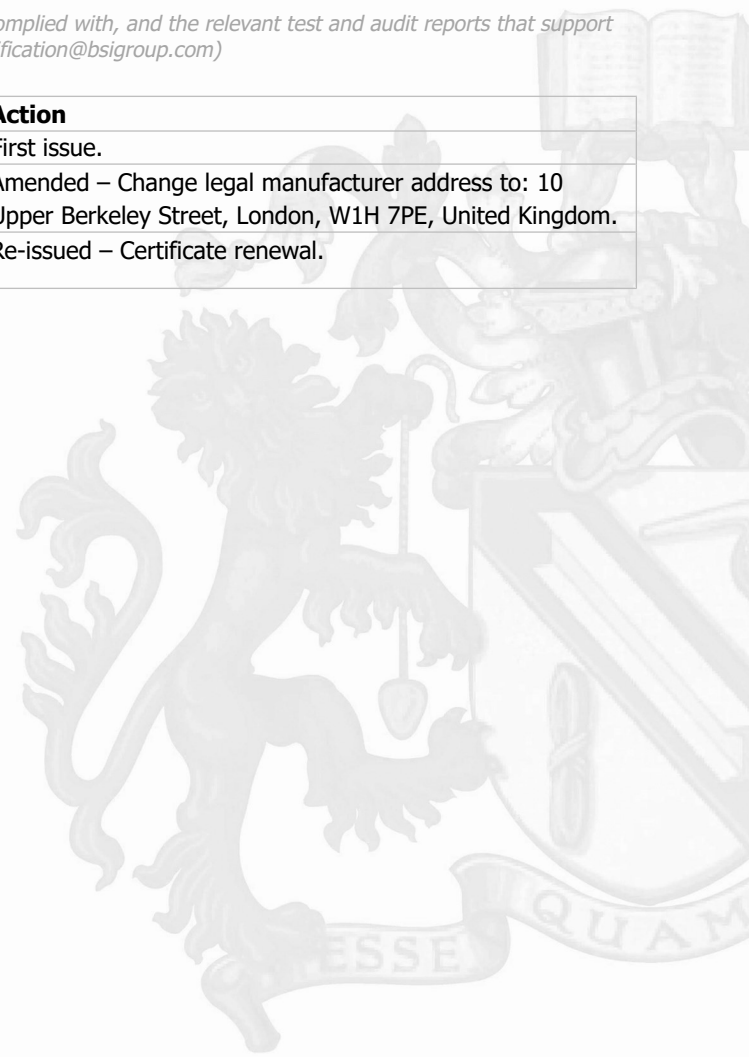
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### Certificate History

*(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
2020-09-17	3147855	First issue.
2024-10-31	30289358	Amended – Change legal manufacturer address to: 10 Upper Berkeley Street, London, W1H 7PE, United Kingdom.
Current	30406759	Re-issued – Certificate renewal.



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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.