

EU Quality Management System Certificate

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

MDR 724463 R000

Manufacturer: Biotronics3D

Address:

5 Greenwich View Place
City Reach, Millharbour
London
E14 9NN
United Kingdom

Single Registration Number: Not Available

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

Address:

Str. Fabrica de Caramida
nr 1A, Lot C, Parcela 36, Sector 1
Bucuresti
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 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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-09-17**

Date: **2020-09-17**

Expiry Date: **2025-09-16**

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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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Device Schedule: Class IIa

Device(s)	Risk Classification
3Dnet	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	3147855	First issue.



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