

NUMBER : 0010  
REVISION : 17.0  
DATE : 06/02/26  
AUTHOR : JC  
APPROVAL : SG

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**DECLARATION OF CONFORMITY**

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Biotronics 3D Limited  
10 Upper Berkeley Street  
London, W1H 7PE  
United Kingdom

**EU DECLARATION OF CONFORMITY**  
Medical devices

We hereby declare that the manufactured CE marked products, specified in the annexed product list, are covered by the "CE Marking of Conformity Certificate", reference: MDR 724463, issued on 17/09/2025 by the BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands, Notified Body Identification Number 2797, and conforms to the requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, concerning medical devices (MDR), and Regulation (EU) 2021/2226 regarding electronic instructions for use of medical devices.

This declaration is based on the application of the ISO 13485:2016 and EN ISO 13485:2016+A11:2021 Quality System approved for the design, development, manufacture and software maintenance of the products concerned. The conformity of the quality assurance system is described in the ISO 13485:2016 and EN ISO 13485:2016+A11:2021 Certificate, reference number: MD 561882, issued and delivered by BSI. The conformity assessment follows the procedure specified in Chapters I and III of Annex IX of the Regulation (EU) 2017/745 (MDR), and including an assessment of the technical documentation as specified in Section 4 of that Annex.

This Declaration of Conformity covers the 3Dnet product family as specified in the product list belonging to this declaration, with Basic UDI-DI, is issued under the sole responsibility of the manufacturer, and is valid for all products concerned bearing the CE marking and manufactured at the following site:

*Name and address of Manufacturer:*

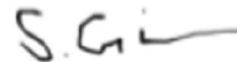
Biotronics 3D Limited, 10 Upper Berkeley Street, London, W1H 7PE, United Kingdom  
SRN: UK-MF-000051724

*Name and address of EU Authorized Representative:*

Skyer Medical Imaging S.R.L., Str. Fabrica de Caramida, nr 1A, Lote C, Parcela 36, Sector 1, Bucuresti, Romania  
SRN: RO-AR-000049393

*Function, name and signature of authorized person.*

Soeren Grimm, CEO



*Place and date of issue*

London, 6<sup>th</sup> February 2026

Annex: Product list



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**PRODUCT LIST**

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Biotronics 3D Limited  
10 Upper Berkeley Street  
London, W1H 7PE  
United Kingdom

**PRODUCT LIST**

3Dnet (Medical Device Class IIa)

Product name 3Dnet  
Product code Version 2.15  
Basic UDI-DI 506075752MEDICALIMAGINGLF

Intended purpose 3Dnet is intended to be used by physicians for archiving, communication and the display of 2D/3D visualisation of DICOM compliant medical image data, such as CT, MR, PT, US, CR, MG, NM, DX, OT, XA, XR, XC, RF, DR, DS, SR, OCT, PX, ECG, ES, IO modalities, and reporting. 3Dnet Viewer provides several levels of medical functionality to the user:

- Basic analysis tools such as 2D review, orthogonal multi-planar reconstructions (MPR, oblique MPR, curved MPR, Slab MPR, AvgIP, MIP, MinIP), measurements, annotations, reporting, distribution, etc.
- Tools for in-depth analysis, such as segmentation, endoscopic view, colour volume rendered slabs, greyscale volume rendered slabs, 3D volume review, path definition and boundary detection.
- Specialist tools and workflow enhancements for specific clinical applications which provide targeted workflows, custom UI, measurement and visualisation; including Virtual Colonoscopy, Vessel Analysis, Calcium Scoring, PET/CT, CT Lung Analysis, CT Dental and DCE-MRI Breast, Bronchoscopy, KiM Graph, and Prostate Module.

3Dnet can be used to display medical imaging data of covered modalities on patient population and medical conditions applied to those modalities.

PACS is essential equipment for radiology departments and practices, both large and small. The traditional radiology department has been constrained in terms of efficiency and cost by the process of dark room processing, film storage, film copying and the process of 'signing out' films by clinicians. Today, PACS has brought down these barriers. Digital imaging has enabled the radiology films and images to be digitised and distributed in digital format. This combined with the use of PACS has effectively given radiologists and clinicians the ability to access the images from anywhere and at any time.

*Place and date of issue*

*Function, name and signature of authorized person.*

London, 6<sup>th</sup> February 2026

Soeren Grimm, CEO

