Biotronics3D Ltd
5 Greenwich View Place
City Reach, Millharbour
London E14 9NN
United Kingdom

DECLARATION OF CONFORMITY

Medical devices

We hereby declare that the distributed CE marked products, specified in the annexed product list, are covered by the "CE Marking of Conformity Certificate", reference: MDR 724463, issued on 17/09/2020 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).

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, manufacture and final inspection 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:
Biotronics3D Ltd, 5 Greenwich View Place, City Reach, Millharbour, London E14 9NN, UK

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

Biotronics 3D
Analyze · Collaborate · Discover
Registered in England and Wales
Reg.number: 5029338
VAT number: 858 4757 67

Place and date of issue
London, 15th March 2022

Function, name and signature of authorized person.
Haralambos Hatzakis, CEO

Annex: Product list

Biotronics3D Ltd
5 Greenwich View Place
City Reach, Millharbour
London E14 9NN
UK

PRODUCT LIST

3Dnet (Medical Device Class IIa)

Product name	3Dnet
Marketed also as	OpenRad Cloud
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 provides several levels of 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 and Prostate.

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, 21st November 2022 — Soeren Grimm, CTO

S. G.

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