



UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No.

UKCA 759344

Issued To:

Adas3D Medical S.L.

Rambia Catalunya 53,4-H

Barcelona 08007 Spain

In respect of:

Design, manufacture and final inspection of medical imaging software in the clinical domain of cardiology

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-01-18** Date: **2023-05-04**

Expiry Date: **2027-01-17**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

This certificate was issued electronically and is bound by the conditions of the contract.





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Supplementary Information to UKCA 759344

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NBOG Code	Device Name	Intended purpose per IFU
Class IIa		
MD 1111	Software to enhance the visualisation and analysis of MRI and CT cardiac images	Not applicable for class IIa devices

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Approved Body Contacts PCT Vitemark Court Days Avenue Vingulaill Milton Voyage Mil





UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: **UKCA 759344**Date: **2023-05-04**

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Barcelona 08007 Spain

Date	Reference Number	Action
2022-01-18	3555993	First Issue; Traceable to CE 714517
Current	3833071	Amended – Change of manufacturer address from "Carrer Paris 179, 2 ^a -2 ^a , Barcelona, 08036, Spain" to "Rambla Catalunya 53, 4-H, Barcelona, 08007, Spain".

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