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.**
Rambla 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: **2024-02-22** Expiry Date: **2027-01-17**

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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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UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: **UKCA 759344**
Date: **2024-02-22**
Issued To: **Adas3D Medical S.L.**
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Date	Reference Number	Action
2022-01-18	3555993	First Issue; Traceable to CE 714517
2023-05-04	3833071	Amended – Change of manufacturer address from "Carrer Paris 179, 2ª-2ª, Barcelona, 08036, Spain" to "Rambla Catalunya 53, 4-H, Barcelona, 08007, Spain".
Current	30113233	Amended – Change of UK Responsible Person (UKRP) to: "AF PHARMA SERVICE UK LTD, Suite 140 Temple Chambers, 3-7, Temple avenue, London, EC4Y 0DA, England, UK."

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