

# 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]

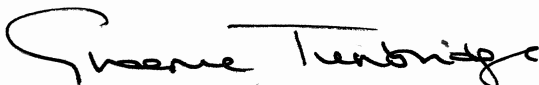
**No.** UKCA 759344  
**Issued To:** Adas3D Medical S.L.  
Rambla Catalunya 53,4-H  
Barcelona  
08007  
Spain

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: **2023-05-04**

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

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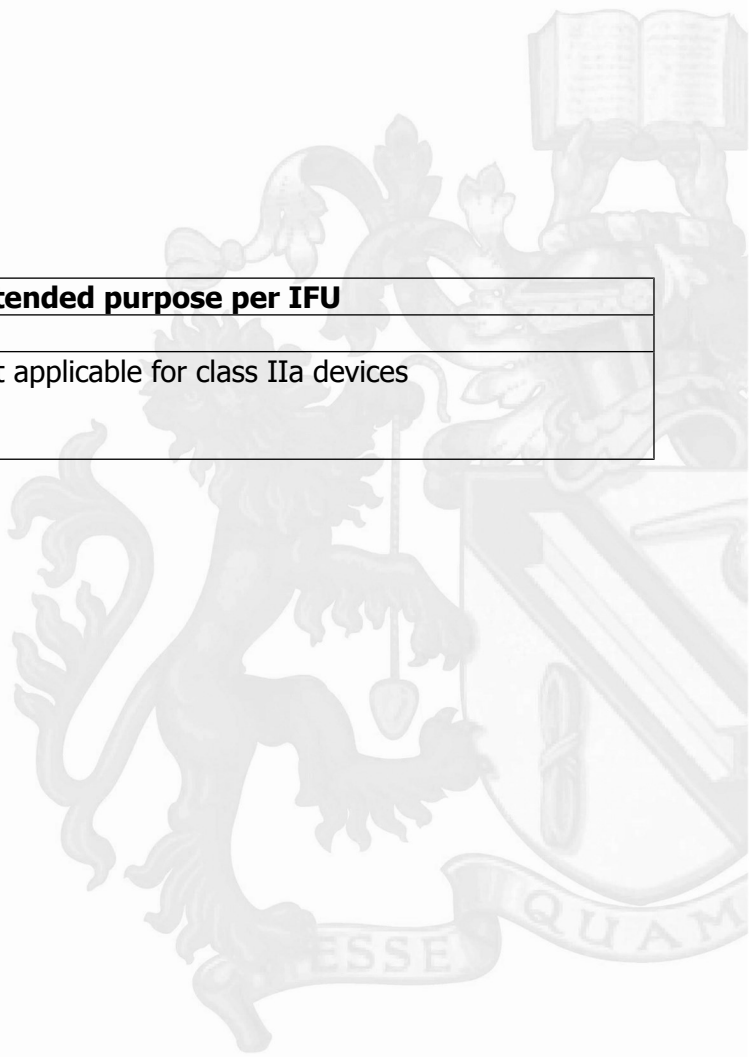
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## Supplementary Information to UKCA 759344

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<b>NBOG Code</b>	<b>Device Name</b>	<b>Intended purpose per IFU</b>
<b>Class IIa</b>		
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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## Certificate History

Certificate No: **UKCA 759344**  
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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 <sup>a</sup> -2 <sup>a</sup> , Barcelona, 08036, Spain” to “Rambla Catalunya 53, 4-H, Barcelona, 08007, Spain”.

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