

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 731107 R000

**Manufacturer:** Adas3D Medical S.L.

**Address:**

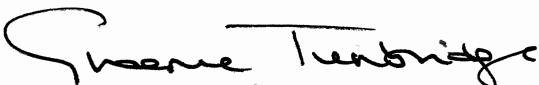
Rambla Catalunya 53, 4-H  
Barcelona  
08007  
Spain

**Single Registration Number:** ES-MF-000000391

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-02-25**

Current Issue Date: **2023-05-03**

Starting Validity Date: **2023-05-03**

Expiry Date: **2027-02-24**

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### Device Schedule: Class IIa

Device(s)	Risk Classification
Medical device imaging software in the clinical domain of cardiology	Class IIa



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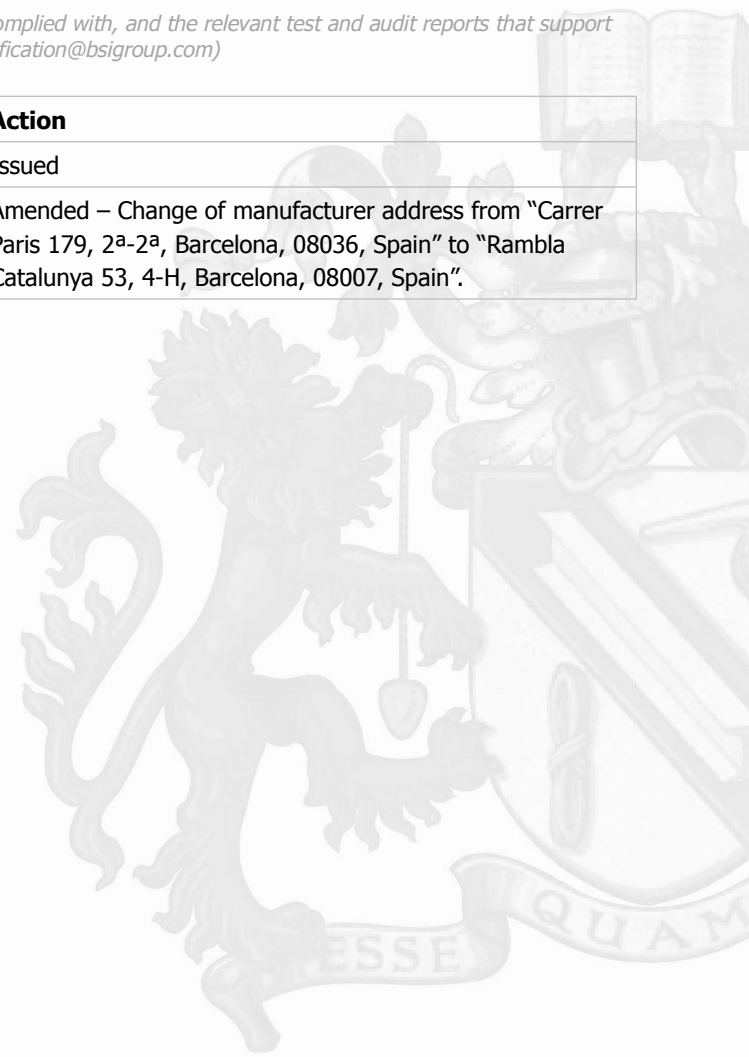
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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference Number	Action
2022-02-25	3247484	Issued
Current	3833064	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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Validity of this certificate is conditional on the Manufacturer’s quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.