

## Medical Device Registration Certificate of P. R. C.

Registration certificate No. 国械注进 20232210618

The name of the registrant	ADAS3D Medical S.L.
The address of the registrant	Carrer Pairs 179, 2a 2a Barcelona 08036 Spain
Manufacture address	Carrer Pairs 179, 2a 2a Barcelona 08036 Spain
The name of China Agent	Shanghai VIACERT Product Technical Services Co., Ltd.
The address of China Agent	Room 101, Building 4, No. 300 Bao Zheng Nan Road, Chongming District, Shanghai
Product name	Medical device imaging software in the clinical domain of cardiology
Type/model	ADAS 3D, release version 2.6
Structure and compose	This product consists of software installation files and authorization files. Its functional modules include LV Enhancement Analysis, LV Thickness Analysis, LA Enhancement Analysis Module, Heart Anatomy Extraction Analysis, Image Alignment Multimodal Tool, Comare 3D Multimodal Tool, Enhancement Quantification tool (LV and LA) and Study Storage Database.
Scope of application	Used for displaying, processing, and measuring CT and MR cardiovascular enhanced images that comply with DICOM standards. It is not intended to identify regions for catheter ablation or treatment of arrhythmias. It is not for clinical decision making.
attachment	Product technical requirements
other	/
remark	

Approval Dept.: NMPA

Approval date: 2023.12.27

Effective date: 2023.12.27

Expiry date: 2028.12.26



# 中华人民共和国医疗器械注册证

注册证编号：国械注进20232210618

注册人名称	ADAS3D医疗有限公司 ADAS3D Medical S.L.
注册人住所	Carrer Paris 179, 2a 2a Barcelona 08036 Spain
生产地址	Carrer Paris 179, 2a 2a Barcelona 08036 Spain
代理人名称	上海沃华产品技术服务有限公司
代理人住所	上海市崇明区堡镇镇堡镇南路300号4幢101室（上海堡镇经济小区）
产品名称	心血管图像处理软件 Medical device imaging software in the clinical domain of cardiology
型号、规格	ADAS 3D，发布版本2.6
结构及组成	该产品由软件安装文件和授权文件组成，功能模块包括左心室增强分析模块、右心室厚度分析模块、左心房增强分析模块、心脏解剖信息提取分析模块、影像配准多模态工具模块、对照3D多模态工具模块、增强量化工具（左心室和左心房）模块和病例研究存储数据库模块。
适用范围	用于符合DICOM标准的CT和MR心血管增强图像的显示、处理、测量。不用于识别导管消融或治疗心律失常的区域，不用于临床决策。
附件	产品技术要求
其他内容	/
备注	

审批部门：国家药品监督管理局



批准日期：二〇二三年十二月二十七日

生效日期：二〇二三年十二月二十七日

有效期至：二〇二八年十二月二十六日