Certificate

Quality Management System EN ISO 13485:2016

Registration No. SX 7090503-1

Certificate Holder AMT Medical Research B.V.

Zonneoordlaan 17 6718 TK Ede Netherlands

Scope Design and Development, Manufacture and Distribution of

non-active implants and catheters for Coronary Artery Bypass

Grafting and their accessories

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

 Report No.
 1119589-20

 Effective date
 2023-05-02

 Expiry date
 2026-05-01

 Issue date
 2023-05-02

This certificate can be validated on https://www.certipedia.com

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Dipl.-Ing. S. Pane TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany





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Quality Management System EN ISO 13485:2016

Registration No. SX 7090503-1

Certificate Holder AMT Medical Research B.V.

Zonneoordlaan 17 6718 TK Ede Netherlands

The scope of certification covers the following sites:

No.	Facility	Scope
/01	AMT Medical Research B.V. Zonneoordlaan 17	Manufacture of catheters for Coronary Artery Bypass Grafting and their accessories. Distribution of non-active implants and catheters for Coronary
	6718 TK Ede Netherlands	Artery Bypass Grafting and their accessories
/02	AMT Medical Research B.V.	Design and Development of non-active implants and catheters for Coronary
	Yalelaan 52	Artery Bypass Grafting and their accessories. Manufacture of non-active
	3584 CM Utrecht	implants for Coronary Artery Bypass Grafting and their accessories.
	Netherlands	

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