Certificate

Quality Management System
EN ISO 13485:2016 + AC:2018 + A11:2021
ISO 13485:2016

Registration No.:	SX 2627294-1
Certificate Holder:	Detechgene GmbH Nattermannallee 1 50829 Köln Germany
Scope:	Design and Development of in-vitro diagnostic analyzer, test kits, and accessories, including near-patient test devices, for the RT-LAMP based detection of transmissible agents.

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.:	1208700-100
Effective date:	2026-08-05
Expiry date:	2029-08-04
Issue date:	2026-08-05

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