Certificate

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

Registration No.:	SX 1530337-1
Certificate Holder:	Operon, SA Camino del Plano, 19 50410 Cuarte de Huerva (Zaragoza) Spain
Scope:	The design and development, manufacture and distribution of in-vitro diagnostic reagents and test kits, including their controls, intended for: predicting the risk and prognosis of genetic diseases or disorders; detecting the presence of, or exposure to, infectious agents including sexually transmitted agents; pregnancy testing; screening, determination, or monitoring of physiological markers; screening, confirmation, determination, or monitoring of allergies and intolerances. The devices are intended for professional use, near-patient testing, and as companion diagnostics. Distribution of in-vitro diagnostic test strip readers.

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.:	92836795-30
Effective date:	2025-09-06
Expiry date:	2028-09-05
Issue date:	2025-09-05

Replaces certificate SX 1530337-1 issued 2022-11-02.

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

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