

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1625253-1
Certificate Holder: SONOTEC GmbH
Thüringer Str. 33
06112 Halle (Saale)
Germany

Scope: Design and development, manufacture and distribution of parts / components for sensors in the medical field of non-contact and non-invasive liquid flow measurement and air bubble detection

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.: 1153105-10
Effective date: 2025-02-03
Expiry date: 2026-04-21
Issue date: 2025-02-03
Replaces certificate SX 1625253-1 issued 2023-04-20.

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

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o SONOTEC GmbH Thüringer Str. 33 06112 Halle (Saale) Germany	Design and development, manufacture and distribution
/02	c/o SONOTEC GmbH Nauendorfer Str. 2 06112 Halle (Saale) Germany	Design and development, manufacture and distribution

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