

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1061479-1

Certificate Holder: ALPHA PLAN GmbH
Juri-Gagarin-Str. 13a
01454 Radeberg
Germany

Scope: Design and development, manufacturing and distribution of
filters for medical applications

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.: 1184777-100

Effective date: 2025-10-24

Expiry date: 2028-10-23

Issue date: 2025-10-13

Replaces certificate SX 1061479-1 issued 2022-10-21



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