

Certificate

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

Registration No.: SX 1325760-1

Certificate Holder: ICU Tech sp. z o.o.
ul. Bytomska 14
81-509 Gdynia
Poland

Scope: Design and development and manufacturing of active non-implantable devices for mechanical stimulation, obstetrics and gynecology measurement devices not included in other classes and components including software, electronics and mechanics.

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.: 84987291-30

Effective date: 2026-04-22

Expiry date: 2029-04-21

Issue date: 2026-04-22

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


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