

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

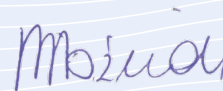
Registration No.: SX 1023950-1
Certificate Holder: HTL-STREFA S.A.
ul. Adamówek 7
95-035 Ozorków
Poland

Scope: Design and development, manufacture and distribution of sterile single-use personal lancets, safety lancets, pen needles, safety pen needles and non-sterile lancing devices.

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.: 84974919-100
Effective date: 2024-08-02
Expiry date: 2027-08-01
Issue date: 2024-08-02



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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	HTL-STREFA S.A. ul. Adamówek 7 95-035 Ozorków Poland	Design and development, manufacture and distribution of sterile single-use personal lancets, safety lancets, pen needles, safety pen needles and non-sterile lancing devices.
/02	HTL-Strefa S.A. ul. Lotnicza 21 99-100 Łęczyca Poland	Design and development, manufacture and distribution of sterile single-use personal lancets, safety lancets, pen needles, safety pen needles and non-sterile lancing devices.

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