

Certificate

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

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.: 84993965-20

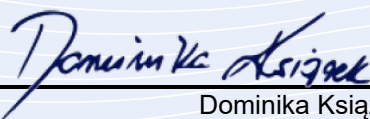
Effective date: 2026-07-22

Expiry date: 2027-08-01

Issue date: 2026-07-22

Replaces certificate SX 1023950-1 issued 2024-08-02

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


Dominika Książek
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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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 and safety lancets. Design and development and distribution of sterile single-use pen needles, safety pen needles and nonsterile lancing devices.
/02	HTL-STREFA S.A. ul. Lotnicza 21h 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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