

Certificate

Certificate No.: MD 1023950-1-2

Manufacturer: **HTL-STREFA S.A.**

Ul. Adamówek 7
95-035 Ozorków
Poland

REPs Facility ID: F007617

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure

Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,
RDC ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282,

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68,
PMD Act

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D.

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.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 84993965-20

Issue Date: 2026-07-22

Effective Date: 2026-07-22

Expiry Date: 2027-08-13



Certification officer: Dominika Książek
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>
or calling 1-888-743-4652.

Certificate

Certificate No.: MD 1023950-1-2
Manufacturer: **HTL-STREFA S.A.**
Ul. Adamówek 7
95-035 Ozorków
Poland

The scope of certification also covers the following sites:

No.	Location	Scope
/01	HTL-STREFA S.A. ul. Adamówek 7 95-035 Ozorków Poland REPs Facility ID: F007617	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 REPs Facility ID: F007619	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 validity of the certificate can be verified on <https://www.certipedia.com>
or calling 1-888-743-4652.