

# Certificate

Certificate No.: MD 1023950-1-1

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, sterile single-use safety lancets, sterile single-use pen needles, sterile single-use safety pen needle 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.: 84974919-90, 84974919-100

Issue Date: 2024-08-14

Effective Date: 2024-08-14

Expiry Date: 2027-08-13



Certification officer: Rafal Byczkowski  
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.

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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, sterile single-use safety lancets, sterile single-use pen needles, sterile single-use safety pen needle and non-sterile lancing devices.
/02	HTL-Strefa S.A. ul. Lotnicza 21 99-100 Łęczyca Poland REPs Facility ID: F007619	Design and development, manufacture and distribution of sterile single-use personal lancets, sterile single-use safety lancets, sterile single-use pen needles, sterile single-use safety pen needle and non-sterile lancing devices.

**TÜV Rheinland**



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