CERTIFICATE

Number: 2194749

The management system of the organization(s) and locations mentioned on the addendum belonging to:

HTL-Strefa S.A.

Ul. Adamówek 7
95-035 Ozorków
Poland

Manufacturer Facility Identifier F000578

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia:	Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil:	RDC ANVISA N. 16/2013, 23/2012 and 67/2009
Canada:	Medical Devices Regulations - Part 1- SOR 98/282
Japan:	MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States:	21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:
Design and development, manufacture and distribution of sterile single use blood lancets, pen needles and lancing devices.

Certificate expiry date:	2025-01-01
Certificate effective date:	2023-01-16
Certified since:	2019-01-28

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M.A. McKenzie
Certification Manager

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
https:/www.dekra-product-safety.com/en/certified-organizations

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra.nl Company registration 09085396

ADDENDUM

To certificate: 2194749

The management system of the organization(s) and/or location(s) of:

HTL-Strefa S.A.

Ul. Adamówek 7
95-035 Ozorków
Poland

Certified organization(s) and/or locations:	Different scope
HTL-Strefa S.A Ul. Lotnicza 21h 99-100 Leczyca Poland Manufacturer Facility Identifier F000578	Design and development, manufacture and distribution of sterile single use blood lancets, pen needles and lancing devices.

Addendum expiry date: 2025-01-01
Addendum effective date: 2023-01-16