

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 DUNS 422528088

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 and Article 4 to Article 68

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.

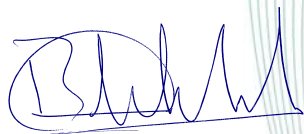
Certificate expiry date: 2022-01-01

Certificate effective date: 2019-01-28

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.A. van Vugt
Certification Manager

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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/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices 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-certification.com 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

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

Addendum expiry date: 2022-01-01

Addendum effective date: 2019-01-28