

CERTIFICATE

Number: 995651

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

including the implementation meets the requirements of the standard:

EN ISO 13485:2012

Scope:

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

Certificate expiry date: 1 March 2019
Certificate effective date: 1 September 2016
Certified since: 25 August 2004

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

DEKRA Certification B.V.

A blue ink signature of G.J. Zoetbrood.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of A.A.M. Laan.

ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 995651

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

HTL-Strefa S.A.

ul. Adamówek 7
95-035 Ozorków
Poland

Certified additional organization(s) and/or locations:

Organization/Location	(Different) Scope
HTL-Strefa S.A Ul. Lotnicza 21h 99-100 Leczyca	Design and development, manufacture and distribution of sterile, single use blood lancets, pen needles and lancing devices.
HTL-Strefa, Inc. 3005 Chastain Meadows Pkwy GA 30066 Marietta United States Of America	Distribution of sterile single-use blood lancets, pen needles and non-sterile lancing devices

Addendum expiry date: 1 March 2019
Addendum effective date: 1 September 2016