

# 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 13485:2016

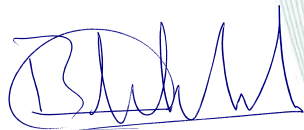
Scope:

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

Certificate expiry date: 1 January 2022  
Certificate effective date: 28 January 2019  
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 B.T.M. Holtus, consisting of a stylized, cursive script.

B.T.M. Holtus  
Managing Director

A blue ink signature of J.A. van Vugt, consisting of a stylized, cursive script.

J.A. van Vugt  
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 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 bloodlancets, pen needles and lancing devices.

Addendum expiry date: 1 January 2022  
Addendum effective date: 28 January 2019