CERTIFICATE

Number: 995651

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

HTL-Strefa S.A.

UI. 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 2025 Certificate effective date: 24 January 2022 Certified since: 25 August 2004

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

Helligh

© 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.

UI. Adamówek 7 95-035 Ozorków Poland

Certified organization(s) and/or locations:

Different scope

HTL-Strefa S.A UI. 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: 1 January 2025 Addendum effective date: 24 January 2022