

CERTIFICATE

Number: 84587CE01

CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

HTL-Strefa S.A.

ul. Adamówek 7
95-035 Ozorków
Poland

For the product category:

Sterile, single use blood lancets and pen needles sterilized by gamma irradiation

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 84587CN, initially dated 15 March 1999
Addendum, initially dated 6 December 2010

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex V in combination with Annex VII for class IIa products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. The necessary information and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 September 2016
Issued for the first time: 15 March 1999
Reissued: 27 August 2013

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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ADDENDUM

Belonging to certificate: 84587CE01

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This certificate covers the following product(s):

Product type	GMDN Code
Type 545-549	37466
Type 550-552	37466
Type 553-556	37466
Type 560	37466
Type 410	37466
Type 420	37466
Type 810	44127
Type 532	37466
Type 430	37466
Type 520	37466
Type 610	37466

Initial date: 6 December 2010
 Revision date: 25 February 2013

DEKRA Certification B.V.



drs. G.J. Zoetbrood
 Managing Director



ing. A.A.M. Laan
 Certification Manager

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