EC CERTIFICATE

Number: 84587CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

HTL-Strefa S.A.

ul. Adamówek 7
95-035 Ozorków
Poland

For the product category(ies)

Sterile, single use blood lancets and pen needles sterilized by gamma irradiation, and non-sterile lancing devices

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 Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities 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 2019
Issued for the first time: 15 March 1999
Reissued: 1 September 2016

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 84587CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Sterile, single use blood lancets and pen needles sterilized by gamma irradiation, and non-sterile lancing devices

Issued to:

HTL-Strefa S.A.
ul. Adamówek 7
95-035 Ozorków
Poland

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 820	44127
Type 532	37466
Type 430	37466
Type 450	37466
Type 520	37466
Type 610	37466
Type 700	37243

Initial date: 6 December 2010
Revision date: 15 August 2015

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

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