

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:

Single use bloodlancets sterilized by gamma irradiation

KEMA 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 March 15, 1999

KEMA 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: September 1, 2010

Issued for the first time: March 15, 1999

Revised: June 15, 2006

Reissued: June 21, 2007

drs. G.J. Zoetbrood
Managing Directordr. ir. G.W. Bos
Certification Manager

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