HTL STREFA
high tech lab

HTL ZJ/161/2010

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95-035 Ozorków
POLAND

DECLARATION OF CONFORMITY
medical devices rev. 30

We hereby declare that the distributed CE marked products, specified in the annexed product list, are covered by the "CE Marking of Conformity Certificate", reference number: 84587CE01 issued for first time on 15th March 1999 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, and conform to the required technical documentation, in accordance with Annex II of the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices and revision of directive 2007/47/EC.

In addition, we ensure and declare that distributed CE market products, as mentioned and falling within Class IIa, meet the provisions of the EU-Directive which apply to them.

This declaration is supported by the Quality System certification based on the harmonized standards:
- CAN/ISO 13485:2003, Quality System Certificate no 2127419 issued first time 01.09.2010 delivered by DEKRA Certification B.V
- EN ISO 13485:2012, Quality Certificate no 995651 issued first time 25.08.2004 delivered by DEKRA Certification B.V

This declaration of Conformity covers sterile, single use lancets, personal lancets, pen needles, lancing devices and is valid for all products concerned bearing the CE marking and manufactured at the following sites:
- Site 1: Ozorków, 7 Adamówek Street, 95-035 Poland,
- Site 2: Łęczyca, Lotnicza Street 21h, 99-100, Poland and

Quality Assurance and Regulatory Affairs Director

Aleksandra Prażmowska-Wilanowska

Ozorków, 2015-06-10