HTL ZJ/161/2010

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

DECLARATION OF CONFORMITY
medical devices rev. 50

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 developed base on the harmonized standards:
- EN ISO 13485:2016, Certificate no. 995651 issued first time 2004-08-25 delivered byDEKRA Certification B.V
- ISO 13485:2016 (MDSAP), Certificate no. 2194749 issued first time 2019-01-28 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, ul. Adamówek 7, 95-035 Poland,
- Site 2: Łęczyca, ul. Lotnicza 21h, 99-100, Poland

Ozorków, 2020-12-10

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PRODUCT LIST rev. 50

Sterile, single use lancets, pen needles; non-sterile, multiple use lancing devices

This product list belongs to the Declaration of Conformity identified by document no HTL ZJ/161/2010 and specifies the CE marked products concerned that HTL-Strefa S.A. intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices and revision of directive 2007/47/EC. The following list identifies the products by name and type and by serial number.

Product type according CE mark certificate / Commercial Name	***Dimension of the needle***	***GMDN code***	***First lot no with CE mark:***
Safety lancet type 520	diamet® mySafety	23G 23G/ 28G/29G 23G/29G 23G/29G 29G	61579	P21M114N3 P21N614N4 S14V714L1
Safety lancet type 553-556	Medlance Plus: (Special, Extra, Lite, Universal, SuperLite)	21G / 25G / 30G 0,8 mm blade	61579	J8C82A6

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Product type according CE mark certificate /	***Commercial Name***	***Dimension of the needle***	***GMDN code***	***First lot no with CE mark:***
Personal lancet type 560	Soft Fine Colour	28G/33G 33G 30G	61579	E6B6 P15B6 T12A4 T53A7
	diamet	31G x 6 mm 31G x 8 mm 29G x 10 mm 29G x 12 mm	44127	

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Product type according CE mark certificate /	***Commercial Name***	***Dimension of the needle***	***GMDN code***	***First lot no with CE mark:***
Safety Pen Needles type 820	diamet® mySafety	31G x 6 mm 31G x 8 mm	44127	V55G9 W55A1

Aleksandra Prażmowska-Wilanowska

Regulatory Affairs Director

Ozorków, 2020-12-10

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REVISION HISTORY

No.	Rev. no.	Page	Change description	Introduced by	Date	Effective date

Ozorków, 2020-12-10

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