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 by DEKRA 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, 2021-01-26

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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 420	Haemolance Plus Safe-T-Lance Plus	18G 21G 25G 28G 1.5 mm blade	61579	M22A313A6 W43F928A8
Safety lancet type 430	Prolance Single-Let	18G / 21G / 25G / 28G 1,5 mm blade 28G	61579	P37K937G5
Safety lancet type 450	ergo®Lance	21G 25G 30G	61579	U50A445A9
Safety lancet type 520	Assure Lance MediSafe Solo MenaLancet Pro Securlancets unik diamet® mySafety MedicoFine	23G 23G/28G/29G 23G/29G 23G/29G 29G	61579	P21M114N3 P21N614N4 S14V714L1
Safety lancet type 532	myLance	23G / 28G	61579	
Safety lancet type 545-549	Medlance	21G / 23G / 28G 1,5 mm blade	61579	B2D33C7 X30B13D5
Safety lancet type 553-556	Medlance Plus: (Special, Extra, Lite, Universal, SuperLite)	21G / 25G / 30G 0,8 mm blade	61579	J8C82A6
	GlucoSmart	21G / 30G	61579	
	Safe Digitest	21G / 25G / 30G	61579	Z50B318C1

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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 lancet type 610	Acti–Lance	17G / 23G / 28G	61579	P25L24K2
	Safe Digitest PLUS	23G / 28G	61579	Z11E443F7
Personal lancet type 560	Droplet Penlancet Soft Fine Colour MenaLancet Microdot MyStar SylkFeel Glucoject Lancets PLUS GlucoSmart fine	28G/30G/33G 28G/33G 33G 30G	61579	E6B6 P15B6 T12A4 T53A7
Lancing device type 700	Droplet MyStar SylkFeel Glucoject Dual PLUS	n/a	37243	1505A02 1711A03
Pen Needles type 810	Droplet / Haemofine / Accu-Fine	32G x 4 mm 32G x 5 mm 32G x 6 mm 32G x 8 mm 31G x 5 mm 31G x 6 mm 31G x 8 mm 29G x 10 mm 29G x 12 mm 30G x 8mm 33G x 4mm 34G x 3,5mm	44127	P39G4 P39J2
	Glucoject Pen Needles	32G x 4 mm 32G x 6 mm 32G x 8 mm 31G x 5 mm 31G x 6 mm 31G x 8 mm 29G x 10 mm 29G x 12 mm	44127	T53A6 W46ZJ5 W46ZJ1
	microdot droplet	32G x 4mm 31G x 6mm 31G x 8mm	44127	X46ZK4
	Standard NanoFine pen needles	32G x 4 mm 32G x 5 mm 32G x 6 mm 32G x 8 mm 31G x 5 mm 31G x 6 mm	44127	
	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	DropSafe diamet® mySafety	31G x 6 mm 31G x 8 mm	44127	V55G9 W55A1
	DIAVUE Prudential			Y55J1
	Safe Block			Z55K7
	MedicoFINE			Z55Y6

Aleksandra Prażmowska-Wilanowska

Regulatory Affairs Director

Ozorków, 2021-01-26

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REVISION HISTORY

No.	Rev. no.	Page	Change description	Introduced by	Date	Effective date
1.	33	All	Safe-T-Lance (Type 420) was added to Declaration of Conformity. Gages and blades added.	J. Żemigala	2017-03-24	2017-03-24
2.	34	All	Medlance 23G (Type 545-549) was added to Declaration of Conformity (refer to CC 79/2017 and CC – 361/2016	P. Potyrała	2017-03-31	2017-04-06
3.	35	All	Brand Single-Let 28G added to the Declaration of Conformity	M. Szwolgin	2017-09-14	2017-09-14
4.	36	All	Change in version Glucoject Dual PLUS (lancing device type 700) – lot number was added to Declaration of Conformity (CC – 312/2017)	J. Żemigala	2017-11-24	2017-02-02
			Brand microdot droplet was added for type 810 (CC 350/2017)	B. Jarosik	2018-01-12	
5.	37	All	Brand Standard NanoFine pen needles added to the Declaration of Conformity (CC 363/2017)	K.Nożewska	2018-01-12	2018-03-01
6.	38	4	- Phrase *Sterile, single use lancet, pen needles, lancing device* changed to *Sterile, single use lancets, pen needles; non-sterile, multiple use lancing devices* - removed: Site 3: HTL-Strefa, Inc. 3005 Chastain Meadows Pkwy Marietta GA 30066 USA – distribution center (ECN-147/2017) - Brand DIAVUE Prudential added to type 820 (CC 65/2018)	I.Banaś J.Żemigała	2018-05-29	2018-06-19
7.	39	2-3	- Change of GMDN Code for blood lancets (safety lancets and personal lancets) from: 37466 to 61579 (CC 9/2018)	J.Żemigała	2018-06-20	2018-08-06
8.	40	3-4	Brand GlucoSmart was added for type 553-556 (CC-351/2018)	J.Żemigała	2018-10-15	2018-10-15
9.	41	2	Typo error related to gage of Safety lancet type 430 has been corrected (23G into 21G)	J.Żemigała	2018-12-06	2018-12-06
10.	42	All	EN ISO 13485:2012 updated into EN ISO 13485:2016 based on new Certificate effective from 2019-01-28. ISO 13485:2016 added as per MDSAP Certificate. New brand myLance implemented and BD Sentry removed within safety lancet type 532 (CC 384/2018) New brands have been added: - Safe Digitest for type 553-556 (CC-458/2018) - Safe Digitest PLUS for type 610 (CC-502/2018) - Safe Block for type 820 (CC-457/2018)	J.Żemigała	2019-01-30	2019-01-30
11.	43	2	Safety lancet type 410 Haemolance Profile (CC – 163/2019) removed.	J.Żemigała	2019-05-22	2019-08-22

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12.	44	2	New brand diamet® mySafety for type 520 added (CC 137/2019)	J.Żemigała	2019-09-06	2019-09-24
13.	45	4	New brand name MedicoFINE included in type 820 (CC 271/2019)	I. Banaś	2019-09-30	2019-10-31
14.	46	3-4	GlucoSmart fine included in type 560 (CC 228/2018). Assencia Microlet, Microlet removed from type 560. Diamet included in type 810 (base on CC 177/2019)	J.Żemigała	2019-11-22	2019-11-22
15.	47	3	Brand name New Line has been removed from type 610, as it is not existing on the market and as well as in Product Specifications	J.Żemigała	2020-04-27	2020-04-27
16.	48	2	New version/gage 28G within Medlance safety lancet type 545-549 has been added	J.Żemigała	2020-06-17	2020-06-17
17.	49	3	New brand: Accu-Fine within type 810 has been added	J.Żemigała	2020-06-18	2020-06-18
18.			New gages 30G, 33G, 34G within type 810 has been added		2020-06-18	2020-10-05
19.	50	2	Brand MedicoFine type 520 added based on CC - 296/2020	I. Banaś	2021-01-21	2021-01-21

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