

RA 133/2024

2024-08-19

EU DECLARATION OF CONFORMITY
medical devices rev. 1

Manufacturer's name: HTL-Strefa S.A,
ul. Adamówek 7,
95-035 Ozorków,
Poland

SRN: PL-MF-000002198

Device's name: safety lancets, personal lancets
(as per the Product list)

Classification: IIa

Classification rule: 6

We, herewith declare under the sole responsibility of the manufacturer that the stated medical devices meet the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

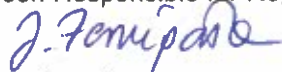
This Declaration of Conformity is supported by the Quality Management System based on the standard for medical devices, confirmed by following Certificates:

- EN ISO 13485:2016, Certificate No.: SX 1023950-1 issued by TÜV Rheinland LGA Products GmbH
- ISO 13485:2016 (MDSAP), Certificate No.: MD 1023950-1-1 issued by TUV Rheinland of North America, Inc.

This Declaration of Conformity is valid for all products concerned bearing the CE Marking of Conformity specified in the annexed product list.

CE marked devices are covered by the EU Certificate Quality Management System, REGULATION (EU) 2017/745 on Medical Devices in accordance with Annex IX, Chapter I, Section 2 and 3, reference number: HZ 1023950-1 issued for first time on 2024-08-02. The certification was delivered by TÜV Rheinland LGA Products GmbH, Tillystraße 2, D-90431 Nürnberg, German, Notified Body Identification Number 0197 on the products concerned conforming to the required Technical Documentation and meeting the relevant provisions of Regulation (EU) 2017/745.

On behalf of HTL-Strefa S.A.
Justyna Żemigala
Regulatory Affairs Manager /
Person Responsible for Regulatory Compliance



Authorized signature, Name & Position

Ozorków,
Place, date 2024-08-19

Medical Technology and Devices S.p.A. ("MTD")

Registered office: Via Saldarini Catelli, 10 – 22070 Casnate con Bernate (CO) – Italy – Share capital € 10.000.000 i.v.
Identification code SDI: USAL8PV Tel: 0039 031 7297111 - Fax: 0039 031 7297100 - PEC medical.technology.devices@legalmail.it
Tax Code, VAT number and Como Business Register number 04062530136 - Registered in the R.E.A. of the C.C.I.A.A. of Como n. 417150
www.mtdglobal.com

HTL-STREFA S.A.

Adamówek 7, PL-95035 Ozorków, Poland T +48 42 270 00 10, www.htl-strefa.pl, info@htl-strefa.pl

VAT: PL7321880362, REGON: 472350579, District Court for Łódź-Sródmieście in Łódź, XX Commercial Department of the National Court Register, KRS: 0000256309,
share capital: 2,934,421.10 PLN (paid in full)

The address for correspondence: HTL-STREFA S.A. Lotnicza 21H, PL-99100 Łęczyca, Poland, T +48 24 721 92 02

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PRODUCT LIST

This product list belongs to the EU Declaration of Conformity identified by document no RA 133/2024 and specifies the CE marked products concerned that HTL-Strefa S.A. intends to distribute in conformity with the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

The following list identifies the products by name and device type.

Device name and type / intended purpose	Commercial Name	Dimension of the needle	GMDN / EMDN code	Basic UDI-DI
Safety lancet type 420 sterile, single-use medical devices intended for capillary blood sampling	- Haemolance Plus - Safe-T-Lance Plus	18G / 21G / 25G / 28G / 1.5 mm blade	61579 / V0104	590799609420M8, 590799609420XFY
	McKesson Safety Lancets PUSH BUTTON	28G		
Safety lancet type 430 sterile, single-use medical devices intended for capillary blood sampling	Prolance	18G / 21G / 25G / 28G 1,5 mm blade	61579 / V0104	590799609430MB, 590799609430XG5
	Single-Let	28G		
Safety lancet type 450 sterile, single-use medical devices intended for capillary blood sampling	ergo Lance	21G / 25G / 30G	61579 / V0104	590799609450MH, 590799609450XGF
Safety lancet type 520 sterile, single-use medical devices intended for capillary blood sampling	MediSafe Solo	23G / 28G / 29G	61579 / V0104	590799609520MD, 590799609520XG7
	- MenaLancet Pro - Securlancets unik	23G / 29G		
	- diamet mySafety - MedicoFine	29G		
	Single-Let Next	28G		
Safety lancet type 532 sterile, single-use medical devices intended for capillary blood sampling	myLance	23G / 28G	61579 / V0104	590799609532ML, 590799609532XGJ

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Effective

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2024-08-19

Device name and type / intended purpose	Commercial Name	Dimension of the needle	GMDN / EMDN code	Basic UDI-DI
Safety lancet type 545-549 sterile, single-use medical devices intended for capillary blood sampling	Medlance	21G / 23G / 28G 1,5 mm blade	61579 / V0104	5907996095455493K, 590799609532XGJ
Safety lancet type 553-556 sterile, single use medical devices intended for capillary blood sampling	Medlance Plus	21G / 25G / 30G 0,8 mm blade	61579 / V0104	5907996095535563, 5907996095535563D
	GlukoSmart	21G / 30G		
	Safe Digitest	21G / 25G / 30G		
	Solofix Safety	21G/25G/ 0,8mm blade		
Safety lancet type 610 sterile, single-use medical devices intended for capillary blood sampling	Acti-Lance	17G / 23G / 28G	61579 / V0104	590799609610MF, 590799609610XG9
	Safe Digitest PLUS	23G / 28G		
Personal lancet type 560 sterile, single-use medical devices intended to be used with a lancing	droplet	28G / 30G / 33G	61579 / V0104	590799609560MR, 590799609560XGT
	Penlancet	28G / 33G		
	MyStar SylkFeel			
	MenaLancet	30G		
	Microdot			
	GlukoSmart fine			
	Glucobject Lancets PLUS	33G		

On behalf of HTL-Strefa S.A.
Justyna Żemigala
Regulatory Affairs Manager /
Person Responsible for Regulatory Compliance


Authorized signature, Name & Position

Ozorków,
Place, date 2024-08-19

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Effective

RA 324/2024
2024-12-11

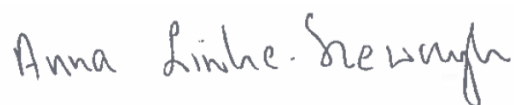
The statement to the EC Declaration of Conformity (DoC No.: RA 133/2024)

We, HTL-STREFA.S.A. with its registered office at Adamówek no. 7, 95-035 Ozorków, Poland hereby declare that,

Solofix Safety Lancet Type 553-556 are covered by the EU Declaration of Conformity (Doc No.: RA 133/2024) EU DoC of Solofix Safety Lancet which we issued and can be placed in the market as a medical device according to the Medical Device Regulation (EU) 2017/745

B.Braun items	HTL items	Product description	EMDN Code
6183010DE	7132	Solofix Safety Fine	61579/V0104
6183020DE	7133	Solofix Safety Neonat	61579/V0104
6183000DE	7131	Solofix Safety Universal	61579/V0104

Yours faithfully,



Anna Linke-Szewczyk
Regulatory Affairs Senior Specialist
Regulatory Affairs Department of HTL-Strefa S.A.

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