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 Żemigała
Regulatory Affairs Manager /
Person Responsible for Regulatory Compliance

J. Żemigała

Ozorków,
Place, date 2024-08-19

Authorized signature, Name &Position

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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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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
	• GlucoSmart	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			
	• GlucoSmart fine			
	• Glucoject Lancets PLUS	33G		

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

J. Żemigała

Ozorków,
Place, date 2024-08-19

Authorized signature, Name &Position

RA 324/2024
2024-12-11

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

We, HTL-STREFA.S.A. with its registered office at Adamowek no. 7, 95-035 Ozorkow, 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.