

EU DECLARATION OF CONFORMITY
medical devices rev. 2

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

SRN: PL-MF-000002198

Device's name: Sterile, single-use pen needles and safety pen needles
(as per the Product list)

Classification: IIa

Classification rule: 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 of the standards on medical devices, confirmed by following applicable Certificates:

- EN ISO 13485:2016, Certificate no. 995651 issued by DEKRA Certification B.V
- ISO 13485:2016 (MDSAP), Certificate no. 2194749 issued by DEKRA Certification B.V

This Declaration of Conformity 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

CE marked devices, specified in the annexed product list are covered by the EU Quality Management System Certificate in accordance with Annex IX, reference number: 225134CE01 issued for first time on 21 November 2022 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, and conform to the required technical documentation.

On behalf of HTL-Strefa S.A.

Justyna Żemigala
Regulatory Affairs Manager /
Person Responsible for Regulatory Compliance



Ozorków,
Place, date 2024-04-03

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 324/2020 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 type according to EU Certificate / intended purpose	Commercial Name	Dimension of the needle	GMDN / EMDN code	Basic UDI-DI
Pen Needles type 810 sterile, single-use medical devices intended for use with pen injector devices for the subcutaneous injection of drugs.	<ul style="list-style-type: none"> droplet HaemoFine 	0.23 mm x 4 mm (32G x 5/32") 0.23 mm x 5 mm (32G x 3/16") 0.23 mm x 6 mm (32G x 1/4") 0.23 mm x 8 mm (32G x 5/16") 0.25 mm x 5 mm (31G x 3/16") 0.25 mm x 6 mm (31G x 1/4") 0.25 mm x 8 mm (31G x 5/16") 0.33 mm x 10 mm (29G x 3/8") 0.33 mm x 12 mm (29G x 1/2") 0.30 mm x 8 mm (30G x 5/16") 0.20 mm x 4 mm (33G x 5/32") 0.18 mm x 3.5 mm (34G x 3.5mm)	44127 / A01010102	590799609810MR
	<ul style="list-style-type: none"> Accu-Fine 	0.23 mm x 4 mm (32G x 5/32") 0.23 mm x 6 mm (32G x 1/4") 0.25 mm x 5 mm (31G x 3/16") 0.25 mm x 6 mm (31G x 1/4") 0.25 mm x 8 mm (31G x 5/16") 0.20 mm x 4 mm (33G x 5/32")		
	<ul style="list-style-type: none"> Glucoject 	0.23 mm x 4 mm (32G x 5/32") 0.23 mm x 6 mm (32G x 1/4") 0.23 mm x 8 mm (32G x 5/16") 0.25 mm x 5 mm (31G x 3/16") 0.25 mm x 6 mm (31G x 1/4") 0.25 mm x 8 mm (31G x 5/16") 0.20 mm x 4 mm (33G x 5/32")		
	<ul style="list-style-type: none"> microdot droplet 	0.23 mm x 4 mm (32G x 5/32") 0.25 mm x 6 mm (31G x 1/4") 0.25 mm x 8 mm (31G x 5/16")		
	<ul style="list-style-type: none"> diamet 	0.25 mm x 6 mm (31G x 1/4") 0.25 mm x 8 mm (31G x 5/16") 0.33 mm x 10 mm (29G x 3/8") 0.33 mm x 12 mm (29G x 1/2")		
	<ul style="list-style-type: none"> AviFine 	0.23 mm x 4 mm (32G x 5/32") 0.23 mm x 5 mm (32G x 3/16") 0.23 mm x 8 mm (32G x 5/16")		

Device type according to EU Certificate / intended purpose	Commercial Name	Dimension of the needle	GMDN / EMDN code	Basic UDI-DI
Safety Pen Needles type 820 sterile, single-use medical devices intended for use with pen injector devices for injection of drugs	<ul style="list-style-type: none"> DropSafe Safe Block diamet mySafety 	0.25 mm x 5 mm (31G x 3/16") 0,25 mm x 6 mm (31G x 1/4") 0,25 mm x 8 mm (31G x 5/16")	44127 / A01010102	590799609820MU
	<ul style="list-style-type: none"> DIAVUE Prudential MedicoFINE 	0,25 mm x 6 mm (31G x 1/4") 0,25 mm x 8 mm (31G x 5/16")		
	<ul style="list-style-type: none"> beurer medical 	0,25 mm x 6 mm (31G x 1/4") 0,25 mm x 8 mm (31G x 5/16")		

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