2026-03-11
RA 324/2020

EU DECLARATION OF CONFORMITY
medical devices rev. 8

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 7

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.: 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 issued for first time on 21 November 2022. The current 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 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

Ozorków,
Place, date 2026-03-11

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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 name and type / 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.	• 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 9/64") 0.18 mm x 4 mm (34G x 5/32")	44127 / A0101010202	590799609810MR 590799609810XGP 590799609810EFH
	• 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") 0.18 mm x 3.5 mm (34G x 9/64")		
	• 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")		
	• 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")		
	• 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")		
	• Clickfine	0.23 mm x 4 mm (32G x 5/32") 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 5 mm (29G x 3/16") 0.33 mm x 10 mm (29G x 3/8") 0.33 mm x 12 mm (29G x 1/2")	44127 / A0101010202	590799609810046R

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Device name and type / 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	• 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 / A0101010201	590799609820MU 590799609820XGU 590799609820EFN
	• DIAVUE Prudential • MedicoFINE	0,25 mm x 6 mm (31G x 1/4") 0,25 mm x 8 mm (31G x 5/16")		
	• beurer medical	0,25 mm x 6 mm (31G x 1/4") 0,25 mm x 8 mm (31G x 5/16")		
	• AutoProtect	0.25 mm x 5 mm (31G x 3/16") 0,25 mm x 8 mm (31G x 5/16"		

On behalf of HTL-Strefa S.A

Justyna Żemigała
Regulatory Affairs Manager /
Person Responsible for Regulatory Compliance

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REVISION HISTORY

No.	Rev. no.	Page	Change description	Introduced by	Date	Effective date
1.	1	All	Introduction DoC due to transition to Medical Device Regulation (EU) 2017/745.	J.Żemigała	2022-11-24	2022-11-24
2.	2	2	Adding new brand: beurer medical for safety pen needle type 820.	J.Żemigała	2024-04-03	2024-04-03
3.	3	1	Update in regards Certificates: EN ISO 13485:2016 and ISO 13485:2016 (MDSAP) issued by TÜV Rheinland, replacing previous one issued by DEKRA Certification B.V.	J.Żemigała	2024-09-05	2024-09-05
4.	4	1	Update in regards to EU Certificate Quality Management System due to transfer from DEKRA Certification B.V.to TÜV Rheinland. Update of EMDN codes.	J.Żemigała	2024-09-26	2024-09-26
5.	5	2, 3	-Adding new Basic-UDI for pen needle within the type 810: 590799609810XGP 590799609810EFH 590799609810046R and new brands: Clickfine -Adding new Basic-UDI for safety pen needle within type 820: 590799609820XGU 590799609820EFN	J.Żemigała	2024-10-28	2024-10-28
6.	6	1-3	-Adding new brand AutoProtect within type 820 (CC - 86/2025)	J.Żemigała	2025-07-07	2025-07-07
7.	7	2	Removal of the brand Diamet within type 810 (CC 98/2025)	J.Żemigała	2026-01-23	2026-01-23
8	8	2	-Adding 34Gx3,5mm within type 810 Accu-Fine (CC 210/2024) -Adding 34Gx4mm within type 810 droplet (CC 310/2025)	J.Żemigała	2026-03-11	2026-03-11