

STATEMENT

HTL-STREFA S.A. is the manufacturer of safety pen needles type 820 which are marketed in the following versions:

0.25 mm x 8 mm (31G x 5/16")

0.25 mm x 6 mm (31G x 1/4")

0.25 mm x 5 mm (31G x 3/16")

Product availability per brand name and per version (gage & length) may vary on various markets.

Safety pen needles have been tested for compliance with standard **EN ISO 11608-2:2012 Needle-based injection systems for medical use -- Requirements and test methods -- Part 2: Needles.**

Based on testing in accordance with Clause 4.9 and 11 of EN ISO 11608-2:2012, compatibility with needle-based injection systems (NIS), hereinafter called pen injector devices can be claimed. Safety pen needles have passed testing required by ISO 11608-2.

A non-exhaustive list of compatible pen injector devices is to be found in the Appendix 1 to this statement (List of pen injector devices compatible with safety pen needles).

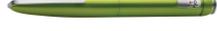
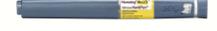
Justyna Żemigala

Regulatory Affairs Manager

Enclosed:

Appendix 1 - List of pen injector devices compatible with safety pen needles manufactured by HTL-STREFA S.A.

Table 1 - Summary of test results on compatibility safety pen needles with needle-based injection system

Standard		EN ISO 11608-2:2012 clause 4.9 & 11	
Needle-based injection system			Test result
Manufacturer / Distributor	Brand name	Product picture	Compatible / Non-compatible
Eli Lilly	HumaPen® MEMOIR		✓
	HumaPen® L U X U R A		✓
	HumaPen® L U X U R A HD		✓
	HumaPen® Ergo		✓
	HumaPen® Ergo II		✓
	HumaPen® savvio		✓
	Humalog® KwikPen™ 200 Units/mL		✓
	ABASAGLAR® KwikPen® 100 Units/mL		✓
Novo Nordisk	NovoPen®4		✓
	NovoPen®3		✓
	NovoPen®5		✓
	NovoPen®6		✓
	NovoPen® Junior		✓
	NovoPen Echo®		✓
	Victoza®		✓
Haselmeier / Berlin-Chemie	BerliPen® PRECISION		✓

	Berli Pen® JUNIOR		✓
Haselmeier / Sanofi-Aventis	TactiPen®		✓
Haselmeier	i-pen®		✓
	JuniorSTAR®		✓
Haselmeier / Berlin-Chemie	Berli Pen® areo 3		✓
Owen Mumford / Berlin-Chemie	Berli Pen® 301		✓
Owen Mumford	Autopen® Classic 3,0 ml x 1 units 1-21 units		✓
	Autopen® Classic 3,0 ml x 2 units 2-42 units		✓
	Autopen® 24 3,0 ml x 1 units 1-21 units		✓
	Autopen®24 3,0 ml x 2 units 2-42 units		✓
Ypsomed	ypsopen®		✓
	БиоматикПен®		✓
Sanofi-Aventis	ClikSTAR®		✓
	Lyxumia® 20 µg		✓
	Toujeo® SoloStar® 300 units/mL		✓
	Lantus® SoloStar® 100 units/mL		✓
	Apidra® SoloStar® 100 units/mL		✓
	ALLStar® PRO		✓
Copernicus / Bioton	GensuPen®		✓
Gani Technology	Xiu Lin Pen		✓
Ypsomed	Gansulin Pen		✓

HTL-STREFA S.A.
Adamówek 7
PL-95035 Ozorkow, Poland
T +48 42 270 00 10
F +48 42 270 00 20
www.htl-strefa.pl
info@htl-strefa.pl

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

4 of 4 ————— 2023-03-23 RA 164a/2020 rev. 4



Ypsomed AG / Polfa Tarchomin S.A.	Polhumin Pen		
--------------------------------------	--------------	--	---

NOTE! The list above is not exhaustive – the brand names may vary on different markets, change due mergers of acquisitions of their owners and private label arrangements.

* - Compatibility with pen injectors is confirmed for existing gauges taking into consideration worst case representative version (8mm). That is why in some cases, a compatibility of safety pen needle differ penetration depth with NIS was sustained base on the positive results of functional tests as fully equivalent with the versions tested.