

# STATEMENT

**HTL-STREFA S.A. is the manufacturer of pen needles type 810 which are marketed in the following versions:**

1. 0.23 mm x 4 mm (**32G x 5/32"**)
2. 0.23 mm x 5 mm (**32G x 3/16"**)
3. 0.23 mm x 6 mm (**32G x 1/4"**)
4. 0.23 mm x 8 mm (**32G x 5/16"**)
5. 0.25 mm x 5 mm (**31G x 3/16"**)
6. 0.25 mm x 6 mm (**31G x 1/4"**)
7. 0.25 mm x 8 mm (**31G x 5/16"**)
8. 0.33 mm x 10 mm (**29G x 3/8"**)
9. 0.33 mm x 12 mm (**29G x 1/2"**)
10. 0.30 mm x 8 mm (**30G x 5/16"**)
11. 0.20 mm x 4 mm (**33G x 5/32"**)
12. 0.18 mm x 3.5 mm (**34G x 3.5mm**)

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

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. 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 pen needles manufactured by HTL-STREFA).












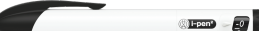






Brand names of pen injector devices are trademarks of their respective owners and may vary on different markets.






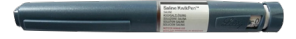













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**Enclosed:**

**Appendix 1 - List of pen injector devices compatible with pen needles manufactured by HTL-Strefa**

**Table 1 - Summary of test results on compatibility pen needles with Needle-based injection system**

Standard		EN ISO 11608-2:2012 clause 4.9 & 11	
Needle-based injection system			Test results
Manufacturer / Distributor	Brand name	Product picture	Compatible /Non-compatible
B. Braun	Omnican®Pen 31		✓
	Omnican®Pen 32		✓
Owen Mumford / Berlin-Chemie	BerliPen® 301		✓
	BerliPen® 302		✓
Haselmeier / Berlin-Chemie	BerliPen® JUNIOR		✓
	BerliPen® areo2		✓
	BerliPen® PRECISION		✓
	BerliPen® areo		✓
	JuniorSTAR®		✓
	TactiPen®		✓
	i-pen		✓
	i-pen®		✓
Copernicus Sp. z o.o / Bioton	GensuPen®		✓
Eli Lilly	Humalog® KwikPen 100 U/ml, 200 U/ml		✓
	HumaPen® Ergo		✓
	HumaPen® Ergo II		✓
	HumaPen® L U X U R A		✓
	HumaPen® L U X U R A HD		✓

Standard		EN ISO 11608-2:2012 clause 4.9 & 11	
Needle-based injection system			Test results
Manufacturer / Distributor	Brand name	Product picture	Compatible /Non-compatible
Eli Lilly	HumaPen® MEMOIR		✓
	HumaPen® savvio		✓
	Humulin® N Pen 100U/ml		✓
	Byetta® Pen		✓
	Abasaglar KwikPen® 100Units/ml		✓
	Saline KwikPen™		✓
	Forteo® 20 µg/80µl		✓
Novo Nordisk	FlexPen®		✓
	FlexTouch®		✓
	NovoLet®		✓
	NovoPen® 3		✓
	NovoPen® 4		✓
	NovoPen® 5		✓
	NovoPen® Echo		✓
	NovoPen® Junior		✓
	Xultophy®		✓
	Victoza® 6mg/ml		✓
	Tresiba® FlexTouch® 200 units/mL		✓
	Levemir® InnoLet® 100 units/ml		✓

Standard		EN ISO 11608-2:2012 clause 4.9 & 11	
Needle-based injection system			Test results
Manufacturer / Distributor	Brand name	Product picture	Compatible /Non-compatible
Owen Mumford	Autopen® 24 3.0 ml x 1 unit 1-21 units		✓
	Autopen® 24 3.0 ml x 2 units 2-42 units		✓
	Autopen® Classic 3.0 ml x 1 unit 1-21 units		✓
	Autopen® Classic 3.0 ml x 2 units 2-42units		✓
Sanofi-Aventis	ClikSTAR®		✓
	OptiPen® Pro1		✓
	OptiPen® Pro2		✓
	SoloSTAR®		✓
	Lantus® SoloStar® 100 units/mL		✓
	Lyxumia® 20 µg		✓
Ypsomed	ypsopen®		✓
Ypsomed / Фармстандарт	БиоматикПен®		✓
Ypsomed / Tonghua Dongbao	Gansulin Pen		✓
BD Medical	PuregonPen®		✓
Gani Technology	Xiu Lin Pen		✓
PENDIQ	pendiq		✓
Diamesco Co., Ltd. / pendiq GmbH	pendiq 2.0		✓

**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.

## REVISION HISTORY

No.	Rev. no.	Page	Change description	Introduced by	Date	Effective date
1.	1.	All	-Revision of document was added. -Page 1: new gages 30G, 33G 34G and description "different private brand names developed for USA/Canadian distributors" was included in the Table 1	J. Żemigala	2020-10-27	2020-10-27