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TECHNICAL DATA SHEET FOR Droplet®

Single-use, sterile pen needles, Type 810

	Date	*Name and Position*	*Signature*
Prepared by	2022-01-04	**Paulina Kowalska** Product Manager	
Verified by	2022-01-05	**Marcin Niemiec** Design Engineer	
Approved by	2022-01-13	**Magdalena Kowalska-Kmieciak** Senior QA Manager	

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1. Administrative information

1.1. Company name:

HTL-STREFA S.A.

Name:	HTL-STREFA S.A.
Address:	ul. Adamówek 7, Ozorków, 95-035 Poland
Phone:	+48 42 270 00 10
Fax:	+48 42 270 00 20
E-Mail:	info@htl-strefa.pl
Website:	www.htl-strefa.com
Commercial reg. No.	KRS 0000256309
Certified standard	EN ISO 13485:2016, , ISO 13485:2016 MDSAP

1.2. Device classification:

The pen needles are classified per rule 6, Annex VIII, of MDR and per rule 6 of Annex IX of MDD as a class IIa product.

For the product assessment Annex IX of MDR and Annex II of MDD are used.

1.3. Notified body:

Conformity of Droplet® single use pen needle. The Quality System is audited for compliance to applicable standards EN ISO 13485:2016 by: DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands.

1.4. Main Supplier

The product currently is sterilized with Gamma rays, however, an alternative method of X-ray (X-Ray) sterilization is in the process of being implemented. As soon as NB approves the X-Ray sterilization method, it will replace the current Gamma sterilization method. The sterilization process is carried out by Steris AST subsidiaries located in the following locations:

Sterilization dose provider location	Sterilization method applied
Synergy Health Radeberg GmbH **a STERIS Company** Juri-Gagarin-Strasse 15, 01454 Radeberg, Germany Tel: +49 (0) 35-284-36-40 e-mail: ast_info@steris.com	gamma irradiation
Synergy Health Ede B.V. **a STERIS Company** Faunalaan 38	x-ray irradiation

Venlo 5928 RZ, The Netherlands Tel: +31 (0) 77 396 1750 e-mail: ast_info@steris.com	
Synergy Health Däniken AG, **a STERIS Company** Hogenweidstrasse 6 CH-4658 Däniken Switzerland Tel: +41 (0) 62288-9060 e-mail: ast_info@steris.com	x-ray irradiation

2. Device family information

2.1. General product description

Droplet® Pen Needles for pen-injectors consist of the following elements:

1. Needle assembly (cannula, thread of the needle hub, needle hub, glue fastening the needle)
2. Needle shield (inner protective cap)
3. Primary container (outer protective cap)
4. Seal (sealing for the outer cap)

Pen needle remains sterile until the seal covering the primary container is removed.

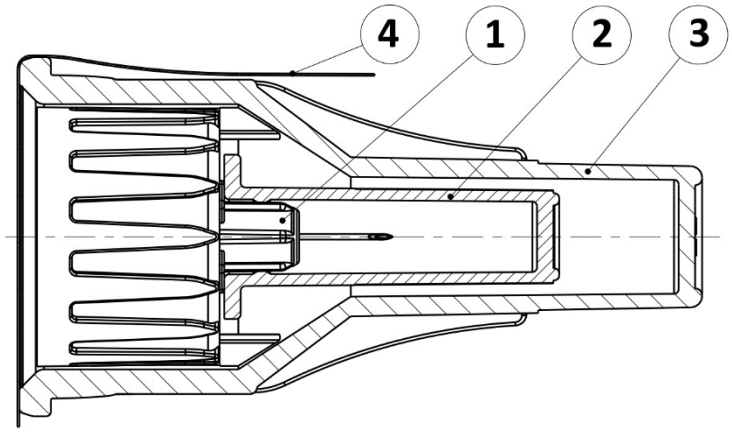
Overall dimensions:

length: 29,1 mm

width: 16,5 mm

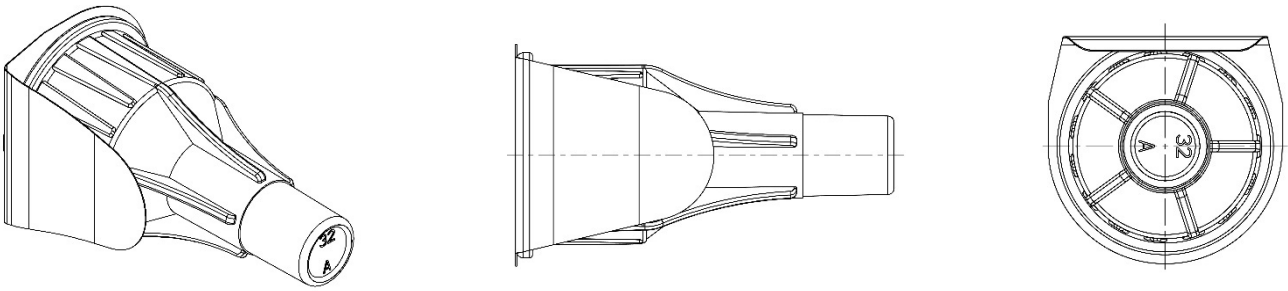
depth: 16,8 mm

Figure A. Droplet® Pen Needle



1. **Needle assembly**
2. **Needle shield**
3. **Primary container**
4. **Seal**

Figure B. Droplet® Pen Needles perspective view



2.2. Product range

Product	Needle shield color
Droplet® Pen Needle 0,23 mm x 4 mm (32G x 5/32'')	Light green
Droplet® Pen Needle 0,23 mm x 5 mm (32G x 3/16'')	Orange
Droplet® Pen Needle 0,23 mm x 6 mm (32G x ¼'')	Light purple
Droplet® Pen Needle 0,23 mm x 8 mm (32G x 5/16'')	Blue
Droplet® Pen Needle 0,25 mm x 5 mm (31G x 3/16'')	Yellow
Droplet® Pen Needle 0,25 mm x 6 mm (31G x ¼'')	Purple
Droplet® Pen Needle 0,25 mm x 8 mm (31G x 5/16'')	Light Blue
Droplet® Pen Needle 0,33 mm x 10 mm (29G x 3/8'')	Green
Droplet® Pen Needle 0,33 mm x 12 mm (29G x ½'')	Pink

List of catalog numbers in an Attachment 1.

2.3. Intended use

Pen needles are sterile, single-use medical devices intended for use with pen injector devices for the subcutaneous injection of drugs. Pen needles are used by healthcare professionals and lay users.

2.4. The method of use

Follow carefully the instructions for use of your pen injector and drug patient information leaflet while preparing for injecting drugs.

1. Remove the seal from the pen needle.
2. Push the pen needle straight on the pen injector devices and twist until it is tight.
   Do not push the pen needle at an angle. Then remove the outer protective cap and set it aside. Do not discard .You will need it later to remove the pen needle from the pen injector devices.
3. Remove the needle cap by pulling it straight out to prevent bending of the needle and/or damaging the needle tip.
4. Prime your pen injector devices as per you pen's instructions for use to prevent incorrect dosage caused by air in the cartridge or a clogged needle. If no drug flow is seen after several attempts, attach a new pen needle.
5. Set your drug dose.
6. Make the injection as directed by your healthcare professional, do not bend the needle. Inject slowly.
   Do not withdraw the needle immediately after injection. Do not change the direction of the pen needle while it remains in the body as this can result in bending or breaking of the needle.
7. Replace the outer protective cap.
8. Remove the pen needle from the pen injector devices after each injection to prevent air from entering the cartridge and drug from leaking out.

2.5. Shelf life

The product shelf life is associated with its sterility. HTL-STREFA S.A. performs accelerated aging and real-time aging tests of pen needles under a shelf life study. . Records are prepared and supervised in accordance with the product specifications for type 810. Basing on the tests results, the manufacturer has decided to give its customers 5 year shelf-life (depending on the market where the product is registered) and assure that the product remains sterile and functional over this period of time.

3. Device component information

Component	Material
Cannula	Stainless Steel Grade AISI 304 (1.4301)
Primary container	Polypropylene
Needle shield	Polypropylene
Needle hub	Polypropylene

Component	Material
Seal	Grid Patterned Lacquer
Shelf box	Cardboard
Shipping box	Corrugated cardboard

4. Packaging information

4.1. Packaging

100pcs carton box (before optimization process)

Shelf box specification:
Material: GC2 cardboard 305 g/m^2 (e.g. ALASKA Plus)
Dimensions: Length: 13 cm Width: 7 cm Height: 7 cm
Weight: 0,14 kg

Shipping box specification:
Material: corrugated cardboard, grey 5W – flute EB, ECT 8000N/m KRAFT
Dimensions: Length: 36,6 cm Width: 26,9 cm Height: 22,8 cm
Weight: 4,4 kg

100pcs carton box (after optimization process)

Shelf box specification:
Material: GC2 cardboard 305 g/m^2 (e.g. ALASKA Plus)
Dimensions: Length: 12,9 cm Width: 8 cm Height: 7,1 cm
Weight: 0,14 kg
Shipping box specification:
Material: corrugated cardboard, grey 5W – flute EB, ECT 9370kN/m KRAFT
Dimensions: Length: 29,9 cm Width: 25,5 cm Height: 28,5 cm
Weight: 3,54 kg

7pcs plastic bag packed into a carton box

Shelf box specification:
Material: GC1 275g/m2
Dimensions:
Length: 9 cm Width: 2.0 cm Height: 7,35 cm
Weight: 0,015 kg.

Case box specification:
Material: GC2 330g/m2
Dimensions:

10pcs plastic bag packed into a carton box

Shelf box specification:
Material: GC1 275g/m2
Dimensions:
Length: 9 cm Width: 2.0 cm Height: 7,35 cm
Weight: 0,018 kg.

Case box specification:
Material: GC2 330g/m2
Diminutions:

Length: 21,5 cm Width: 18,4 cm Height: 7,9 cm
Weight: 0,031 kg.

Shipping box specification:
Material: Corrugated cardboard 5ply type EB 640g/m2
Dimensions:
Length: 39 cm Width: 23,3 cm Height: 17,6 cm
Weight: 1,20 kg.

Length: 21,5 cm Width: 18,4 cm Height: 7,9 cm
Weight: 0,37 kg.

Shipping box specification:
Material: Corrugated cardboard 5ply type EB 640g/m2
Dimensions:
Length: 39 cm Width: 23,3 cm Height: 17,6 cm
Weight: 1,50 kg.

4.2 Transport packaging

100pcs carton box (before optimization process)

1 Shelf box	contains 100 pcs
1 Shipping box	contains 30 shelf boxes = 3000 pcs
Pallet EUR1 80 x120 cm	contains 64 shipping boxes = 1 920 shelf boxes = 192 000 pcs
Pallet EUR2 100 x 120 cm	contains 88 shipping boxes = 2 640 shelf boxes = 264 000 pcs

100pcs carton box (after optimization process)

1 Shelf box	contains 100 pcs
1 Shipping box	contains 24 shelf boxes = 2 400 pcs
Pallet EUR1 80 x120 cm	contains 84 shipping boxes = 2 016 shelf boxes = 201 600 pcs
Pallet EUR2 100 x 120 cm	contains 112 shipping boxes = 2 688 shelf boxes = 268 800 pcs

7pcs and 10pcs carton box

1 Shelf box	**contains 7 pcs**	**contains 10 pcs**
1 Case box	contains 20 shelf boxes = 140 pcs	Contains 20 shelf boxes = 200 pcs
1 Shipping box	contains 4 case boxes = 80 shelf boxes = 560 pcs	contains 4 case boxes = 80 shelf boxes = 800 pcs
Palette EUR1 80 x120 cm	contains 100 shipping boxes 400 case boxes 8 000 shelf boxes = 56 000 pcs	Contains 100 shipping boxes 400 case boxes 8 000 shelf boxes = 80 000 pcs
Palette EUR2 100x120cm	contains 120 shipping boxes 480 case boxes 9 600 shelf boxes = 67 200 pcs	contains 120 shipping boxes 480 case boxes 9 600 shelf boxes = 96 000 pcs

5. Manufacturing process

Needle silicone coating

After gluing the needle into the needle hub and prior to mounting needle shield cannulas are coated with silicone. This process is executed in cleanroom conditions as per ISO Class 8 (which is equivalent to class 100.000 according to USA Federal Std. 209 E).

Molding and Assembly:

Production of plastic parts takes place in area controlled to the requirements of ISO 13485. Pen needles components' manufacturing process is statistically controlled by QC Department. Control process description can be found below in section 7.

Assembly process is carried out automatically in accordance with appropriate instructions. The cannula is placed inside the needle hub and is glued. After that cannula is coated with silicone, dried and then the needle shield is mounted on the needle assembly. Next the primary container is mounted and the seal is welded to the container. Assembled pen needles are loaded in bulk into a commercial packaging as per section 4 of this document.

6. Sterilization

Sterilization is performed in accordance with ISO 11137 and ISO / TS 13004 (previously AAMI TIR 33).

HTL-STREFA S.A. is provided with irradiation certificates for each batch of sterilized product.

Method of sterilization: Gamma ray irradiation

Irradiation source: Cobalt 60

Minimum irradiation dose: 17,5 kGy

Method of assessing process: Dose Quality Audits

Release requirements: Verification of irradiation records – irradiation certificates

7. Device testing

Raw materials as well as packaging materials, excluding printed sales boxes, are inspected at incoming and released for production by Logistics Department based on Supplier's certificates. All materials used to manufacture needle-containing elements and printed sales boxes are tested by the Quality Control for accordance with specifications.

In-process inspection:

Plastic molded elements are checked for defects, short shots, flashes and other parameters. Cannulas are inspected for bluntness, burrs, contamination and other parameters. Assembled pen needles are tested for needle shield pull-out force, primary container removal force, needle protrusion length, cannula's pull-out force, needle orientation and other parameters. They also undergo visual inspection for color and dimensions.

Packaged product is verified for correct lot number, labeling, expiry date and quantity.

Product is released when required tests and Device History Record are compliant with the plant procedures. A Certificate of Conformity is issued for each lot.

Quality control inspection:

Pen needle samples from each batch are assessed by Quality Control (QC). Samples are collected in accordance with the requirements of the EN ISO 11608-2 standard based on product specification type 810.

8. Results of the Risk Analysis

The results of the risk analysis demonstrate that appropriate risk analyses have been performed, the risks are considered to be minimal and they are acceptable when weighed against the intended benefits to the patient. Risk analysis is done according to EN ISO 14971.

9. Applicable Technical Standards

Current list of Applicable Technical Standards for the pen needles and other products manufactured by HTL-STREFA S.A. is supervised and updated internally in the document: Appendix 3 to P01p11 List of applicable standards.

9.1. Harmonized Standards with regard to the European Directive 93/42/EEC on “Medical devices"

9.1.1. Quality Management and Risk Management

Standard	
EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971	Medical devices – Application of risk management to medical devices

9.1.2. Labeling

Standard	
EN ISO 15223-1*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN 1041 (new revision EN 1041+A1 - not harmonized)	Information supplied by the manufacturer with medical devices

9.1.3. Device safety (sterility, biocompatibility, biological evaluation)

Standard	
EN ISO 11137-1	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
EN ISO 11137-2	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.
EN ISO 11607-1	Packaging materials and systems for medical devices which are to be sterilized – Part 1: General requirements and test methods
EN ISO 11737-1	Sterilization of medical devices – Estimation of the population of micro-organisms on product – Part 1: Requirements
EN ISO 11737-2	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

9.1.4. Clinical Evaluation

Standard	
EN ISO 14155	Clinical investigation of medical devices for human subjects - Good clinical practice

9.2. Other relevant technical standards for pen needles

Standard	
EN ISO 11608-2	Pen-injectors for medical use -- Part 2: Needles -- Requirements and test methods
PN-EN 7864	Sterile hypodermic needles for single use
PN-EN ISO 9626	Stainless steel needle tubing for the manufacture of medical devices
ISO/TS 13004 ANSI/AAMI/ISO TIR13004	Sterilization of health care products -- Radiation -- Substantiation of selected sterilization dose: Method VDmaxSD
EN ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and sensitisation
EN 60068-2-31	Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens
IEC 60068-2-30	Environmental testing - Part 2-30: Tests - Test Db: Damp heat, cyclic (12 h + 12 h cycle)
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F2096-11	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F88 / F88M-15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ISO 2859-1	Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptable quality limit (AQL) for lot-by-lot inspection.

10. Revision history

No	CC No.	Revision No.	Page	Description of change	Changed by:	Date	Effective date:
1.	FZ 392/2010	1draft	All	Introduction of Technical File for pen needle type 810	Jacek Karbowniczek	2010-08-12	20.08.2010
2.	FZ 537/2010	1	All	-Changes to the document: Technical File Droplet pen needles, Draft. Changes complement product information by adding detailed data (after product registration and preparation of technical documentation - from Draft to Issue 1)	Edyta Zabierzowska	23.12.2010	
				Added description of the authors of the doc., revised doc. no. ; replacement of the norm PN EN 552 by the norm PN-EN ISO 11137 ; replacement of the old norm by PN-ISO 2859-1 ; change in the doc title from Edition to Revision, doc. page no update ; transport packaging texture change, acc. to KZK - 118/2010 – into corrugated cardboard, grey 5W flute "B+C", 630 g/m2	Edyta Zabierzowska	18.01.2011	
				p.3, change from Medical paper 1102 into Grid Patterned Lacquer, acc to KZK-72/2010	Edyta Zabierzowska	19.01.2011	
				Update of Point 9.: "Applicable Technical Standards"	Edyta Zabierzowska	14.02.2011	
				Change of minimum sterilization dose into 17,5 / 25 kGy and Update of Point 9.: "Applicable Technical Standards"	Edyta Zabierzowska	22.02.2011	28.02.2011
3.	FZ 182/2012	2	All	-Adjustment to current Technical File template - up date of Notify Body's address - addition of new product version 32G 4mm - delete of point 2.5 Intended users -new way of presenting packaging information (remove of all drawings and drawing numbers)	K. Skupin	04.07.2012	27.08.2012
4.	CC-35/2013	3	All 9	Adjustment to current Technical File template. Device product description – new drawings.	J. Morozowska	2013-06-14	2013-07-19
5.	CC-378/2013	4	3 4 5 8 11	Par. 1 Update of EN ISO 13458 to 2012 edition. Par. 2.1 Figure A drawing actualization. Par. 2.2 New pen needle versions added. Par. 9 Standards update. Att.1 List of catalog numbers added	J. Morozowska	2014-07-01	2014-07-02
6.	CC-193/2014	5	All 12	Name of the document changes to Technical Data Sheet. Att.1 List of catalog numbers updated	J. Morozowska	2014-08-08	2014-08-25
7.	CC-225/2014	6	All	Par. 1.2 for product assessment: Annex V and VII to Annex II changed Par. 1.4 Main supplier address data updated Par. 2.2 Added info: List of catalog numbers in an Attachment 1. Par. 2. 3 Added "Commonly used to treat people with diabetes who often require multiple daily insulin injections." – this was deleted from par. 2.4 Par. 2.5 Shelf life information updated. Par. 4 Packaging & transport information updated. Catalog numbers for Canada added. Par. 9 Standards updated	K.Jusewicz	2015-01-07	2015-01-16
8	CC-17/2015	7	All	Par 1.3 Dekra address updated Par 4&Attachment: Catalog numbers updated for USA and Mexico also added Cat. no. for Chile.	K.Jusewicz	2015-05-25	2015-06-08
9	CC - 421/2015	8	All	Par 1.2 Device classification - deleted rule 11 Par 2.1 General product description – updated Pat.2.2 Product range – needle shield color names updated Par 2.3 Intended use – updated Par 2.4 The method of use –updated Par 4.0 Packaging information – updated Par 5.0 Manufacturing process – updated Par 6.0 Sterilization	J.Morozowska	2016-06-02	2016-08-23

				Par 7.0 Device testing - quality control inspection added Par 9.2 Other relevant technical standards for pen needles – updated Attachment 1 - updated			
10	CC – 145/2016	9	13	Attachment 1 – catalog numbers for Macedonia and Australia	J.Morozowska	2016-09-06	2016-11-24
11	CC – 307/2015	10	6	2.5 Shelf life – shelf life changed to a range from 3 to 5 year guarantee	J.Morozowska	2017-01-04	2017-01-27
12	CC – 394/2016	11	5	2.4 The method of use: Point 3 changed to: Remove the inner protective cap by pulling it straight out to prevent bending of the needle.	J.Morozowska	2017-03-14	2017-07-10
13	CC – 190/2017	12	6 13	4.1. Packaging information – material for 100 pcs shipping box changed from: corrugated cardboard, grey 5W flute “B+C”, 630 g/m2; to: corrugated cardboard, grey 5W – flute EB, ECT 8000N/m KRAFT. – weight for 7pcs and 10pcs boxes updated Attachment 1 - catalog numbers for Ukraine added.	J.Morozowska	2017-07-14	2017-10-10
14	CC – 289/2017	13	5	2.3 Intended use – changed from insulin to subcutaneous injection of drugs. Attachment 1 - catalog numbers for Ukraine updated. Catalog numbers for Taiwan.	J.Morozowska	2018-04-18	2018-04-30
15	CC – 289/2017	14	5 9-10 13-14	2.3 Indended use range changed according to different market registrations. 9 Standards updated Attachment 1 - catalog numbers for US (110pcs), Prisoma and China.	J. Morozowska K. Kardyka	2018-07-26	2018-11-23
16	CC – 149/2019	15	5 6-8 14-15	2.3 Intended use update 4.1- 4.2.Transport packaging information update Attachment update – catalog number for Russia, Poland and Nigeria added, 90pcs for USA added, catalog numbers for China updated, catalog numbers for Chile (100pcs and 10pcs deleted)	K. Grychtoł	2019-12-05	2019-12-16
17	CC – 317/2020	16	3 15	1.1. Company name/ 1.3. Notified body – updated Attachment 1 update –USA VA for 32Gx4; 31Gx5; 31G x 8; 29G x 12	A.Romanowska	2021-01-12	2021-02-08
18	CC - 45/2021	17	15	Attachment 1 update – catalog number for Latvia added for 31G x 8, 31G x 6, 32G x 4 100pcs.	P.Kowalska	2021-04-15	2021-05-07
19	CC – 40/2021	18	3, 9	Par. 1.4 Update and information of x-ray sterilization	P.Kowalska	2021-04-29	2021-08-13
20	CC – 143/2021 CC – 40/2021	19	15 3, 10	Attachment 1 update catalog number added for whole product range for Belgium and the Netherlands Par. 1.4 Update and information of x-ray sterilization	P.Kowalska	2021-09-21	2021-12-21
21	CC-324/2021	20	17	Attachment 1 update – catalog number for China 31Gx6, 31Gx8, 29Gx10, 29Gx12, 32Gx4, 100 pcs; Item 2.4 – updated method of use, item 6 – updated standards	P.Kowlaska	2022-01-04	2022-01-20

Attachment 1

PRODUCT		100 pcs CATALOG NUMBER												
	EUROPE	MACEDONIA	UKRAINE	USA	USA VA	MEXICO	CANADA	BRAZIL	CHINA	TAIWAN	SAUDI ARABIA	AUSTRALIA	PRISOMA	POLAND
Droplet®Pen Needle 0,23 mm x 4 mm (32G x 5/32'')	8014	8640	8139	8315	7496	8060	8081	8091	9119	9421	8558	8374	8355	7490
Droplet®Pen Needle 0,23 mm x 5 mm (32G x 3/16'')	8116	8641	8976	8314	n/a	8521	8153	8529	n/a	9422	8557	8373	8358	7491
Droplet®Pen Needle 0,23 mm x 6 mm (32G x 1/4'')	7217	8642	8975	8313	n/a	8522	8154	8530	n/a	9423	8556	8372	8356	7492
Droplet®Pen Needle 0,23 mm x 8 mm (32G x 5/16'')	8118	n/a	8974	8312	n/a	8523	8155	8531	n/a	9424	8555	8371	8357	7493
Droplet®Pen Needle 0,25 mm x 5 mm (31G x 3/16'')	8119	8643	8972	8310	7497	8524	8156	8532	n/a	9425	8554	8370	n/a	7494
Droplet®Pen Needle 0,25 mm x 6 mm (31G x 1/4'')	8013	8644	7749	8311	n/a	8061	8082	8092	9116	9426	8553	8369	n/a	8037
Droplet®Pen Needle 0,25 mm x 8 mm (31G x 5/16'')	8012	n/a	7750	8309	7498	8062	8083	8093	9117	9427	8552	8368	n/a	8038
Droplet®Pen Needle 0,33 mm x 10mm (29G x 3/8'')	8011	n/a	7751	8307	n/a	8063	8084	8094	n/a	9428	8551	8367	n/a	8039
Droplet®Pen Needle 0,33 mm x 12mm (29G x 1/2'')	8010	n/a	7752	8308	7499	8064	8085	8095	n/a	9429	8550	8366	n/a	8040

PRODUCT		100 pcs CATALOG NUMBER		
	RUSSIA	NIGERIA	LATVIA	BELGIUM THE NETHERLANDS
Droplet®Pen Needle 0,23 mm x 4 mm (32G x 5/32'')	8014	8698	7893	8784
Droplet®Pen Needle 0,23 mm x 5 mm (32G x 3/16'')	8116	8697	n/a	8783
Droplet®Pen Needle 0,23 mm x 6 mm (32G x 1/4'')	7217	8696	n/a	8782
Droplet®Pen Needle 0,23 mm x 8 mm (32G x 5/16'')	8118	8695	n/a	8781
Droplet®Pen Needle 0,25 mm x 5 mm (31G x 3/16'')	8119	8694	n/a	8780
Droplet®Pen Needle 0,25 mm x 6 mm (31G x 1/4'')	8033	8693	7892	8779
Droplet®Pen Needle 0,25 mm x 8 mm (31G x 5/16'')	8034	8692	7891	8778
Droplet®Pen Needle 0,33 mm x 10mm (29G x 3/8'')	8035	8691	n/a	8777
Droplet®Pen Needle 0,33 mm x 12mm (29G x 1/2'')	8036	8690	n/a	8776

PRODUCT	10 pcs CATALOG NUMBER					7 pcs CATALOG NUMBER	
	USA	MEXICO	CHILE	BRASIL	CANADA	CHINA (Sinopharm)	CHINA
Droplet®Pen Needle 0,23 mm x 4 mm (32G x 5/32'')	8353	8124	8273	8111	7436	8507	9069
Droplet®Pen Needle 0,23 mm x 5 mm (32G x 3/16'')	8352	8125	8272	8112	7435	n/a	n/a
Droplet®Pen Needle 0,23 mm x 6 mm (32G x 1/4'')	8351	8126	8271	8113	7434	n/a	n/a
Droplet®Pen Needle 0,23 mm x 8 mm (32G x 5/16'')	8350	8127	8270	8114	7433	n/a	n/a
Droplet®Pen Needle 0,25mm x 5 mm (31G x 3/16'')	8348	8128	8268	8115	7432	n/a	n/a
Droplet®Pen Needle 0,25mm x 6 mm (31G x 1/4'')	8349	8129	8269	8117	7431	8135	n/a
Droplet®Pen Needle 0,25mm x 8 mm (31G x 5/16'')	8347	8131	8267	8140	7430	8136	n/a
Droplet®Pen Needle 0,33mm x 10mm (29G x 3/8'')	8345	8133	8265	8141	7429	8137	n/a
Droplet®Pen Needle 0,33mm x 12mm (29G x 1/2'')	8346	8134	8266	8142	7428	8138	n/a

PRODUCT	110 pcs CATALOG NUMBER
	USA
Droplet®Pen Needle 0,23 mm x 4 mm (32G x 5/32'')	9080
Droplet®Pen Needle 0,23 mm x 5 mm (32G x 3/16'')	9081
Droplet®Pen Needle 0,23 mm x 6 mm (32G x 1/4'')	9082
Droplet®Pen Needle 0,23 mm x 8 mm (32G x 5/16'')	9083

PRODUCT	90pcs CATALOG NUMBER
	USA
Droplet®Pen Needle 0,23 mm x 4 mm (32G x 5/32'')	7866
Droplet®Pen Needle 0,23 mm x 8 mm (32G x 5/16'')	7869
Droplet®Pen Needle 0,25mm x 5 mm (31G x 3/16'')	7870
Droplet®Pen Needle 0,25mm x 8 mm (31G x 5/16'')	7872
Droplet®Pen Needle 0,33mm x 12mm (29G x 1/2'')	7874

PRODUCT	100pcs CATALOG NUMBER
	CHINA
Droplet®Pen Needle 0,23 mm x 4 mm (32G x 5/32'')	9370
Droplet®Pen Needle 0,33 mm x 10 mm (29G x 3/8'')	9368
Droplet®Pen Needle 0,25mm x 6 mm (31G x 1/4'')	9366
Droplet®Pen Needle 0,25mm x 8 mm (31G x 5/16'')	9367
Droplet®Pen Needle 0,33mm x 12mm (29G x 1/2'')	9369