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1. Administrative information

1.1. Company data

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

1.3. Notified body

Conformity of Clickfine pen needles: The Quality System is audited for compliance to applicable standards EN ISO 13485:2016 by: TÜV Rheinland LGA Products GmbH (0197); Tillystraße 2, 90431 Nürnberg, Germany.

1.4. Main Supplier

The product is sterilized using Gamma irradiation.

Sterilization dose provider location	Sterilization method applied
BGS Beta-Gamma-Service GmbH & Co. KG Fritz-Kotz-Strasse 12 DE-51674 Wiehl Germany Tel. : +49 (0) 2261 78990 e-mail : info@bgs.eu	gamma irradiation

2. Device family information

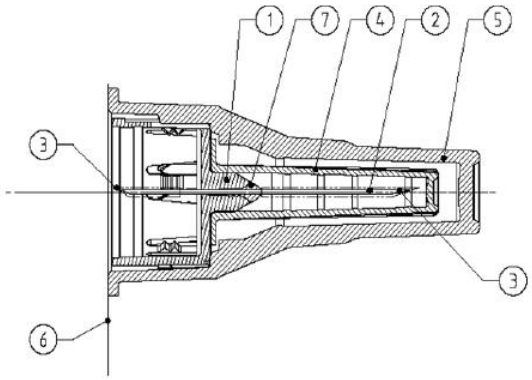
2.1. General product description

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

1. Needle hub
2/3. Cannula (with silicone coating) – needle hub
4. Inner protective cap – needle shield
5. Outer protective cap – needle container
6. Seal
7. Jointing medium – glue

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



1. Needle hub
2/3. Cannula (with silicone coating)
4. Inner protective cap (short/long)
5. Outer protective cap
6. Seal
7. Glue

Figure A. Clickfine® Pen Needle

2.2. Product range

Product	Needle cap color	Seal color
Clickfine Pen Needle 0.23 mm x 4 mm (32G x 5/32”)	White	Light purple
Clickfine Pen Needle 0.25 mm x 5 mm (31G x 3/16”)	White	Yellow
Clickfine Pen Needle 0.25 mm x 6 mm (31G x 1/4")	White	Blue
Clickfine Pen Needle 0.25 mm x 8 mm (31G x 5/16”)	White	Orange
Clickfine Pen Needle 0.33 mm x 10 mm (29G x 3/8”)	White	Turquoise
Clickfine Pen Needle 0.33 mm x 12mm (29G x 1/2")	White	Pink

List of catalog numbers in Attachment 1.

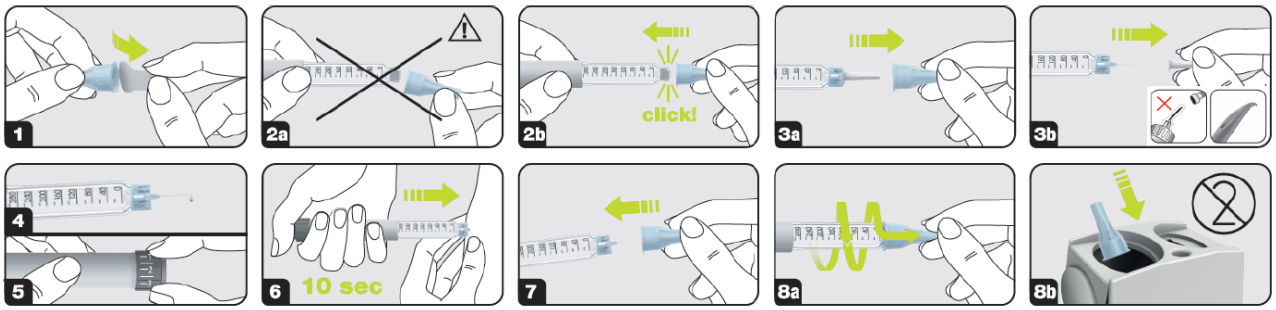
2.3. Intended use

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.



Instructions for use:

1. Remove the seal from the pen needle.

2a. Do not push the pen needle at an angle.

2b. Push the pen needle straight on the pen injector device until you hear a click. The needle can also be screwed onto the injector. When you feel slight resistance, it means that it is securely attached.

3a. 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 device.

3b. Remove the inner protective cap by pulling it straight out to prevent bending of the needle and/or damaging the needle tip.

4. Prime your pen injector device 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. Count to 10 before removing the needle from the skin to deliver a complete dose and to prevent a drug leakage. 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.

8a. Pen needle is single-use only, unscrew the pen needle from the pen injector device after each injection to prevent air from entering the cartridge and the drug from leaking out.

8b. Discard used pen needle into a sharps container.

Warning:

Remove both the outer protective cap and the inner protective cap before an injection. If both the outer cap and the inner protective cap are not removed before use, the medication or dose may not be injected, which may result in serious injury or death.

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. Based 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 assures that the product remains sterile and functional over this period of time.

3. Device component information

Application	Component
Complete needle	Injection needle (cannula) Tube: Stainless Steel Glue: Urethane acrylates Needle hub: Polypropylene (PP) with Masterbatch blue Lubricant: Medical grade silicone
Inner protective cap	Polyethylene (PE) with Masterbatch white
Outer protective cap	Polypropylene (PP) with Masterbatch blue
Pre-printed seal	Polyethylene terephthalate (PET)

4. Packaging information

4.1. Packaging

100pcs carton box

Shelf box specification:
Material: GC2 cardboard 305 g/m2 (e.g. ALASKA Plus)
Dimensions (inside): Length: 129 cm; Width: 71 cm; Height: 80 cm
Weight: 0,13 kg

Shipping box specification (except France):
Material: corrugated cardboard, grey 5W – flute EB, ECT 9370kN/m KRAFT
Dimensions(inside): Length: 29 cm; Width: 24,7 cm; Height: 28,4 cm
Weight: 3,54 kg

Shipping box specification (France):
Material: C-flute corrugated board
Dimensions(inside): Length: 30 cm; Width: 25,5 cm; Height: 14,2 cm
Weight: 1,77 kg

33pcs carton box

Shelf box specification:
Material: Carton GC2 - Alaska Plus 280 g/m2
Dimensions (inside): Length: 80 cm; Width: 70 cm; Height: 71 cm
Weight: 0,49 kg

Shipping box specification:
Material: 5-layer corrugated board, FEFCO 201, flute EB/BE ECT min 9,6 kN/m
Dimensions(inside): Length: 37,3 cm; Width: 24,9 cm; Height: 22,9 cm
Weight: 3,54 kg

Bulk
Shelf box specification:
Material: BC flute corrugated board
Dimensions: (inside) length: 57,8 cm, width: 37,8 cm; height: 24,6 cm
Weight: 10350g

4.2 Transport packaging

100pcs carton box (Export, DACH)

1 Shelf box	**contains 100 pcs**
1 Shipping box	contains 24 shelf boxes = 2 400 pcs
Pallet EUR1 80 x120 cm	contains 36 shipping boxes = 864 shelf boxes = 86 400 pcs
Pallet EUR2 100 x120 cm	contains 48 shipping boxes = 1152 shelf boxes = 115200 pcs

100pcs carton box (France)

1 Shelf box	**contains 100 pcs**
1 Shipping box	contains 12 shelf boxes = 1 200 pcs
Pallet EUR1 80 x 120 cm	contains 84 shipping boxes = 1 008 shelf boxes = 100 800 pcs
Pallet EUR2 100 x120 cm	contains 112 shipping boxes = 1344 shelf boxes = 134400 pcs

100pcs carton box (USA)

1 Shelf box	**contains 100 pcs**
1 Shipping box	contains 24 shelf boxes = 2 400 pcs
Pallet EUR1 80 x120 cm	contains 112 shipping boxes = 2 688 shelf boxes = 268 800 pcs

33pcs carton box (USA)

1 Shelf box	**contains 33 pcs**
1 Shipping box	contains 45 shelf boxes = 1 485 pcs
Pallet EUR1 80 x120 cm	contains 96 shipping boxes = 4 320 shelf boxes = 142 560 pcs

Bulk

1 Shipping box	contains 9500 pcs
Pallet EUR1 80 x120 cm	contains 24 shipping boxes = 228 000 pcs

5. Manufacturing process

5.1 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).

5.2 Molding and Assembly

Production of plastic parts takes place in an 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.

The 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 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
Established minimal sterilization dose: Microbiological Initial Validation
Confirmation of maintain sterilization dose: dose audits
Dose distribution: PQ dose mapping
Release requirements: Verification of irradiation records – irradiation certificates

7. Device testing

Raw materials as well as packaging materials, printed sales boxes, are inspected at incoming and released for production by Logistics Department based on Supplier's certificates.

7.1 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.

7.2 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 2859-1 standard based on product specification for 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 for the patient. Risk analysis is done according to EN ISO 14971:2019.

The process of risk analysis did not identify any unacceptable risks. Product is well established and recognized by international standards which force the manufacturer to use standardization in design and production process.

The main recognized leading manufacturers try to develop the gages and length of the needle appropriate for different users taking into consideration their different needs. Pen needle was developed in the early 90's with new technology for drug delivery. Pen injector, which allows patient to inject the proper dose of drugs using an appropriate construction of pen needle, allows to eliminate hypodermic needle and syringes. Pen needle is a well-recognized product worldwide. Its safety and performance were confirmed in many clinical trials. The risk connected with our product can be acceptable and comes mostly from the production process and specific behaviors of the users connected with following the IFU.

The benefit for the patient is finally having a proper delivery system consisting of pen injector + pen needle, which allows to properly control the hypoglycemia and monitor the diabetes. In current global increase of diabetic problem any new product allowing to make the daily insulin/drug delivery easier becomes the benefit for huge population.

The clinical use of the pen needles as per intended use shall be considered as safe and equivalent to general state of the art.

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"

Standards used to assesment of product - PEN NEEDLES	
1. Harmonized Standards with regard to the European Directive 93/42/EEC on "Medical devices" as amended by Medical Device Directive 2007/47/EC	
EN ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes (ISO 13485:2016) including **EN ISO 13485:2016/AC:2018** Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971:2012*	Medical devices -- Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 15223-1:2016*	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013**) including EN ISO 11137-1:2015/A2:2019** Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices Amendment 2: Revision to 4.3.4 and 11.2 (ISO 11137-1:2006/Amd 2:2018)
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
EN ISO 11737-1:2006	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006) including **EN ISO 11737-1:2006/AC:2009** Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006/Cor 1:2007)
EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009) including **EN ISO 10993-1:2009/AC:2010** Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process - Technical Corrigendum 1 (ISO 10993-1:2009/Cor 1:2010)
EN ISO 10993-4:2009	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006)
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)

EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)'
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020).
EN 62366:2008	Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)
2. Harmonized Standards with regard to the Medical Device Regulation (EU) 2017/745	
EN ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013) including **EN ISO 11137-1:2015/A2:2019** Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 2: Revision to 4.3.4 and 11.2 (ISO 11137-1:2006/Amd 2:2018)
EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
EN ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018) including **EN ISO 11737-1:2018/A1:2021** Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products - Amendment 1 (ISO 11737-1:2018/Amd 1:2021)
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) including **EN ISO 13485:2016/AC:2018** Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) including **EN ISO 13485:2016/A11:2021 Medical devices -** Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN ISO 14971:2019	Medical devices -- Application of risk management to medical devices (ISO 14971:2019) including **EN ISO 14971:2019/A11:2021** Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019) including **EN ISO 11607-1:2020/A1:2023** Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013) including **EN ISO 11137-2:2015/A1:2023** Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose - Amendment 1 (ISO 11137-2:2013/Amd 1:2022)
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)' including **EN ISO 10993-18:2020/A1:2023** Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process - Amendment 1: Determination of the uncertainty factor (ISO 10993-18:2020/Amd 1:2022)
EN ISO 10993-10:2023	Biological evaluation of medical devices – Part 10: Tests for skin sensitisation (ISO 10993-10:2021)

EN ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014) including EN ISO 11135:2014/A1:2019 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E, Single batch release (ISO 11135:2014/Amd 1:2018)
EN 556-1:2024	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices
3. Not harmonized European Directive 93/42/EEC on "Medical devices" as amended by Directive 2007/47/EC and Medical Device Regulation (EU) 2017/745	
EN ISO 20417:2021	Information supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017) including ISO 10993-4:2017/Amd 1:2025
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 13004:2022	Sterilization of health care products -- Radiation -- Substantiation of selected sterilization dose: Method VDmaxSD
ISO 2859-1:1999	Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptable quality limit (AQL) for lot-by-lot inspection. (with amendment 1)
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
ASTM F88/F88M-23	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1929-23	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM D4169 -23	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
IEC 60068-2-30:2005	Environmental testing - Part 2-30: Tests - Test Db: Damp heat, cyclic (12 h + 12 h cycle)
IEC 60068-2-30:2025	Environmental testing - Part 2-30: Tests - Test Db: Damp heat, cyclic (12 h + 12 h cycle)
EN 60068-2-31:2008	Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
IEC TR 62366-2:2016	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices (with A1:2020)
EN ISO 7864:2016	Sterile hypodermic needles for single use - Requirements and test methods (ISO 7864:2016)
EN ISO 11608-2:2012	Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles (ISO 11608-2:2012)
EN ISO 11608-2:2022	Needle-based injection systems for medical use - Requirements and test methods - Part 2: Double-ended pen needles (ISO 11608-2:2022)

EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods (ISO 9626:2016)
ISO 11137-1:2025	Sterilization of health care products — Radiation Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements with Amd 1:2025
EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008) including EN ISO 10993-7:2008/A1:2022 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants (ISO 10993-7:2008/Amd 1:2019)
4. Recognized Consensus Standards associated with FDA (US)	
ISO 15223-1 Fourth Edition 2021-07	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements
AAMI ANSI ISO 15223-1:2016	Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements
ISO 14971: 2019-12 Third edition	Medical devices - Application of risk management to medical devices
AAMI ANSI ISO 14971:2019	Medical devices - Applications of risk management to medical devices
ISO 2859-1 Second edition 1999-11-15	Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection [Including: Technical Corrigendum 1 (2001), Amendment 1 (2011)]
IEC 62366-1 Edition 1.1 2020-06	Medical devices - Part 1: Application of usability engineering to medical devices (consolidated version)
AAMI ANSI IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices +AMD1:2020
ISO 11137-1 Second edition 2025-04	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
AAMI ANSI ISO 11137-1:2006/(R) 2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2019)]
ISO 11137-2 Third edition 2013-06-01	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose [Including AMD1:2022]
AAMI ANSI ISO 11137-2:2013	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
ISO 11607-1 Second edition 2019-02	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including AMD1:2023]
AAMI ANSI ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
AAMI ANSI ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of the population of microorganisms on product
ISO 11737-1 Third edition 2018-01	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products [Including AMD1:2021])]

ISO 11737-2 Third edition 2019-12	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
AAMI ANSI ISO 11737-2:2019	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ASTM F1980-21	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
ASTM F88/F88M-23	Standard Test Method for Seal Strength of Flexible Barrier Materials
ISO 14155 Third edition 2020-07	Clinical investigation of medical devices for human subjects - Good clinical practice
AAMI ANSI ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
AAMI ANSI ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 10993-4 Third edition 2017-04	Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood
AAMI ANSI ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interaction with blood
AAMI ANSI ISO 10993-5:2009/(R) 2014	Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
ISO 10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Fourth edition 2021-11	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
AAMI ANSI ISO 10993-10:2010/(R)2014	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-11 Third edition 2017-09	Biological evaluation of medical devices Part 11: Tests for systemic toxicity
AAMI ANSI ISO 10993-11:2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
ISO 23908 Second Edition 2024-12	Sharps injury protection - Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration - Requirements and test methods
ISO 11608-2:2022	Needle-based injection systems for medical use - Requirements and test methods - Part 2: Double-ended pen needles
ISO 7864 Fourth edition 2016-08-01	Sterile hypodermic needles for single use - Requirements and test methods
ISO 9626 Second edition 2016-08-01	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods

ISO 20417 First edition 2021-04 Corrected version 2021-12	Medical devices - Information to be supplied by the manufacturer
ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)

10. Revision history

No	CC No.	Revision No.	Description of change
1	CC - 266/2025	1	Initial release

Attachment 1 – Catalog numbers

	CATALOG NUMBER (100 pcs)					
PRODUCT / MARKET	**Clickfine Pen Needle 0.23 mm x 4 mm (32G x 5/32")**	**Clickfine Pen Needle 0.25 mm x 5 mm (31G x 3/16")**	**Clickfine Pen Needle 0.25 mm x 6 mm (31G x 1/4")**	**Clickfine Pen Needle 0.25 mm x 8 mm (31G x 5/16")**	**Clickfine Pen Needle 0.33 mm x 10 mm (29G x 3/8")**	**Clickfine Pen Needle 0.33 mm x 12mm (29G x 1/2")**
DACH[1]	7785	7793	7794	7795	9734	9761
France	7792	7796	7797	7798	7799	9760
USA/Canada	9751	7809	9749	9728	-	-
Export 1[2]	7788	7803	9745	9729	9735	9762
Export 2[3]	7791	7808	7807	9740	9738	9765
Israel	7789	7804	9746	9730	9736	9764
Belgium	7790	7806	9748	9731	9737	9763
Australia	9750	7805	9747	9732	-	-

[1]DACH – Germany, Austria, Switzerland
[2]Export 1 – Netherlands, Tunisia, Spain, Bahrain, Bulgaria, Greece
[3]Export 2 – Croatia, Bosnia and Herzegovina, Sweden, Denmark, Iceland, Estonia, Singapore, United Kingdom, Norway, Slovenia

	CATALOG NUMBER (33 pcs)
PRODUCT / MARKET	**Clickfine Pen Needle 0.25 mm x 5 mm (31G x 3/16")**
USA	9727