Products: 3-part sterile single use syringes with and without needles

Sub chapter: 0010	Regulatory requirements
10	Manufacturing site certificated according to ISO 13485 either ISO 9001 ISO 13485 - Medical devices - Quality management systems; ISO 9001 - Quality management systems
20	ISO 7886-1 - Sterile hypodermic syringes for single use - Part 1: Syringes for manual use ISO 7864 – Sterile hypodermic needles for single use
30	ISO 8537 – Sterile single-use syringes, with or without needle, for insulin valid only for insulin syringes
40	Classification of the product according to 93/42/EWG Ism / Rule 2 for syringes w/o needles IIa / Rule 6 for syringes with needles

Sub chapter: 0020	Design of single parts
10	Material and color of the barrel PP (polypropylene), random copolymer containing a slip agent as lubricant, color according to drawing, Suitable for food contact and disposable syringes
20	Nozzle of the barrel Luer according to ISO 594-1 / DIN EN 20594-1 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment; Luer Lock according to ISO 594-2 / DIN EN 1707 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings Oral tip: according to drawing, not compatible with Luer / Luer Lock fittings
30	Printing of the barrel according to drawing
40	Lubricant according to ISO 7886-1 resp. ISO 8537 for insulin syringes erucic and/or oleic acids max. 0.6% (m/m) of the barrel mass
50	Siliconization according to ISO 7886-1 resp. ISO 8537 for insulin undiluted polydimethylsiloxane max. 0,25 mg/cm² of the barrel inside surface
60	Material and color of three-piece plungers 0,5 - 1 ml - PS (polystyrene) or PP (polypropylene) 2 - 100 ml - PP (polypropylene), homopolymer color according to drawing
70	Material and color of piston polyisoprene rubber, latex free, color according to drawing

80	Needles needles according to ISO 7864 - Sterile hypodermic needles for single use; color marking according to ISO 6009 - Hypodermic needles for single use
90	Material and color of needle cap PE (high density polyethylene) or PP (polypropylene), color according to drawing
100	Material and color of protective end cap PE (high density polyethylene) or PP (polypropylene), color according to drawing
110	Material and color of hub PP (polypropylene), color according to drawing
120	Design of needle tube according to ISO 9626
Sub chapter: 0030	**Physical qualities**
10	Dead space of syringe according to ISO 7886-1 1 ml: <= 0.07 ml 2 ml: <= 0.07 ml 3 ml: <= 0,07 ml 5 ml: <= 0.075 ml 10 ml: <= 0.10 ml 20 ml: <= 0.15 ml 30 ml: <= 0.17 ml 50 ml: <= 0.20 ml 100 ml: <= 0.20 ml
20	Dead space of insulin syringe according to ISO 8537 without needle: <= 0.07 ml with attached needle: <= 0.10 ml with jointed needle: <= 0.01 ml
30	Accuracy of dosage by nominal capacity graduation line according to ISO 7886-1 1 ml: ± 0.05 ml 2 ml: ± 0.1 ml 3 ml: ± 0,15 ml 5 ml: ± 0.2 ml 10 ml: ± 0.4 ml 20 ml: ± 0.8 ml 30 ml: ± 1,2 ml 50 ml: ± 2 ml 100 ml: ± 4 ml

40	Accuracy of dosage by nominal capacity graduation line according to ISO 8537 for insulin syringes 0,5 ml: ± 0,025 ml 1 ml: ± 0.05 ml
50	Tightness at vacuum according to ISO 7886-1, annex B resp. ISO 8537, annex B for insulin syringes The syringe is air-tight between piston and barrel at min. 88 kPA below atmospheric pressure, the piston remains at the plunger
60	Tightness at pressure according to ISO 7886-1, annex D resp. ISO 8537, annex F for insulin syringes The syringe is fluid-tight at following pressures <= 10 ml: 300 kPa > 10 ml: 200 kPa
70	Shelf life, sterile product 5 years
80	Light transmission rate for Oral Dispenser syringes: The maximum light transmission rate is 7.449% and minimum light transmission rate is 5.377%. Detail below mentioned:

Acceptance criteria		light transmission rate < 10%			Number of samples		10			
No.	1	2	3	4	5	6	7	8	9	10
Wavelength	450	450	450	450	450	450	450	450	450	450
Light transmission rate (%)	6.702	7.010	7.411	5.377	6.435	6.503	6.776	6.108	7.449	6.479

Sub chapter: 0040	**Chemical qualities**
10	Chemical examinations according to ISO 7886-1 resp. ISO 8537 for insulin syringes - limits for acidity or alkalinity - limits for extractable metals
20	Chemical examinations according to European Pharmacopoeia section "3.2.8." - Solution - Appearance of solution - Acidity or alkalinity - Silicone oil - - Reducing substances
30	Chemical examinations at needles - Acidity or alkalinity - Heavy metals - Cadmium - Resistance to corrosion

Sub chapter: 0050	Biological qualities
10	Barrel according to ISO 10993: - haemolysis (ISO 10993-4) - cytotoxicity (ISO 10993-5) - irritation (ISO 10993-10) - sensitization (ISO 10993-10) - systemic toxicity (ISO 10993-11)
20	Three-piece plunger according to ISO 10993: - cytotoxicity (ISO 10993-5)
30	Piston according to ISO 10993: - haemolysis (ISO 10993-4) - cytotoxicity (ISO 10993-5) - irritation (ISO 10993-10) - sensitization (ISO 10993-10) - systemic toxicity (ISO 10993-11)
40	Needle according to ISO 10993 - haemolysis (ISO 10993-4) - cytotoxicity (ISO 10993-5) - irritation (ISO 10993-10) - sensitization (ISO 10993-10) - systemic toxicity (ISO 10993-11)
50	Protective cap for cannula according to ISO 10993 - cytotoxicity (ISO 10993-5)
60	Protective cap for plunger according to ISO 10993 - cytotoxicity (ISO 10993-5)
70	Hub according to ISO 10993 - cytotoxicity (ISO 10993-5)
80	Pyrogene Non-pyrogenic
90	Latex latex free
100	PVC / plasticizers PVC free / plasticizers free
110	Phthalate Phthalate-free
120	BPA Bisphenol A (BPA)-free (free of Polycarbonate)

130	REACH (1907/2006) Does not contain any substances outlined in the SVHC-list.
140	Precontamination < 100 cfu per product
150	Sterilization with ethylenoxide according to EN 550 - Sterilization of medical devices; Validation and routine control of ethylene oxide sterilization; ISO 11135 - Medical devices - Validation and routine control of ethylene oxide sterilization
160	Recommended sterilization during further processing ethylenoxide other sterilization methods may have influence on mechanical properties, turbidity, discoloration and particles
170	Residual gas analysis according to ISO 10993-7 - Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

Sub chapter: 0060	**Packaging**
10	Labeling of primary container according to ISO 7886-1 or ISO 8537 for insulin syringes, symbols according EN 980: Labeling Standard sterile: Description of content, nominal capacity, type of nozzle, the word "sterile", the words "for single use" or equivalent, LOT-No., expiry date, name, trademark, trade name or logo of the manufacturer or supplier Labeling bulk unsterile: Description of content, nominal capacity, type of nozzle, number, the word “non sterile”, LOT-No., name and address of manufacturer or supplier
20	Primary container standard sterile: heat sealed peel-off blister package consisting of composite PP/PA/PE or PA/PE film backed by medical grade paper Primary container according to ISO 11607-1 Primary container bulk unsterile: Polybag in corrugated card board covered with polybag foil on the inside transport wrapping
30	Labeling of secondary container & transport wrapping according to ISO 7886-1 or ISO 8537 for insulin syringes, symbols according to EN 980: Labeling Standard sterile: description of content, nominal capacity, type of nozzle, number, the word "sterile", the words "for single use" or equivalent, note regarding examination of integrity, LOT-No., expiry date, name and address of manufacturer or supplier, information for handling, transportation and storage
40	Secondary container standard sterile: cardboard box
50	Transport wrapping standard sterile: Corrugated cardboard box
60	Packing contents primary container: Standard sterile: one piece per sterile blister pack Bulk unsterile: 1 mL: 5.000 pcs per transport wrapping 2 mL: 4.000 pcs 5 mL: 2.500 pcs 10 mL: 1.500 pcs 20 mL: 800 pcs 30 mL: 800 pcs

70	Packing contents secondary container: Standard sterile: 1 mL - 20 mL: 100 pcs 30 mL: 100 pcs 50 mL: 50 pcs 100mL: 30 pcs Standard Oral Dispenser Syringes: 1 mL: 100 pcs 3 mL 100 pcs 5 mL 100 pcs 10 mL 100 pcs
80	Packing contents transport wrapping standard sterile: 1 mL: 2.400 pcs (24 secondary container) 2 mL: 2.400 pcs (24 secondary container) 5 mL: 2.000 pcs (20 secondary container) 10 mL: 1.200 pcs (12 secondary container) 20 mL: 900 pcs (9 secondary container) 30 mL: 900 pcs (9 secondary container) 50 mL: 400 pcs (8 secondary container) 100 mL: 180 pcs (6 secondary container) Packing contents transport wrapping standard sterile: 1 mL: 400 pcs (4 secondary container) 3 mL: 400 pcs (4 secondary container) 5 mL: 400 pcs (4 secondary container) 10 mL: 400 pcs (4 secondary container)
90	Storage conditions: Store at room temperature, protect against moisture and sunlight

Remark for bulk packaged syringes:

Bulk packaged unsterile syringes are not considered as medical devices. Sections: 80, 160, 170 and 180 of sub chapter 0050 do not apply.

Products: 3-part sterile single use syringes with and without needles

Intended Use:

The single-use syringes are used for intravenous, intramuscular, subcutaneous, intracutaneous and intraarterial injection of liquids or diluted drugs in combination with an adequate medical device or for withdraw fluids from the body.

The standard oral dispenser syringes are applicable to syringes used for delivering drug or food to oral or enteral.

General information:

Additional regulations

This specification provides basic information for the requirements for the needles and their packaging. Additional requirements must be communicated and agreed upon in writing.

Further processing of the needles

The customer himself is responsible for each way of further processing of the delivered needles.

The specifications are subject to change without prior notice.

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