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 7886-2 - Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps 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 2 for syringes for use with power-driven syringe pumps 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
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) 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), color according to drawing
100	Material and color of protective end cap PE (high density polyethylene), 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

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 - Absorbance - Reducing substances - Transparency/Opalescence
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	BSE / TSE The used materials are produced using petrochemical processes and are not of animal origin. If additives derived from animal sources (tallow) are used in the production of these plastic materials and this medical device/s they undergo a series of rigorous process steps (temperature >200° C, time >20 min., under pressure) which according to European Pharmacopoeia 5th Edition, Chapter 5.2.8 "Minimizing the Risk of Transmitting Animal Spongioform Encephalopathy Agents via Medicinal Products" are considered to be effective TSE inactivation processes.

160	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
170	Recommended sterilization during further processing ethylenoxide other sterilization methods may have influence on mechanical properties, turbidity, discoloration and particles
180	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: 7.000 pcs per transport wrapping 2 mL: 6.300 pcs 5 mL: 3.600 pcs 10 mL: 2.000 pcs 20 mL: 1.000 pcs 30 mL: 800 pcs
70	Packing contents secondary container: Standard sterile: 1 mL - 20 mL: 100 pcs 30 mL: 60 pcs 50 mL: 50 pcs 100mL: 30 pcs
80	Packing contents transport wrapping standard sterile: 1 mL: 1.800 pcs (18 secondary container) 2 mL: 2.500 pcs (25 secondary container) 5 mL: 2.000 pcs (20 secondary container) 10 mL: 1.200 pcs (12 secondary container) 20 mL: 800 pcs (8 secondary container) 30 mL: 600 pcs (10 secondary container) 50 mL: 300 pcs (6 secondary container) 100 mL: 180 pcs (6 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.

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.

Instructions for use:

- If the packaging is damaged or opened the product should not be used due to potential impairment of the sterility conditions.
- Plunger or plunger rod should never be pulled beyond the proximal safety stop. Plunger should not be removed. The safety stop is a noticeable stop at the proximal end of the barrel to prevent accidental spills.
- Once used do not re-use or re-sterilize.

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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.

REVISIONS OF DOCUMENT:

Revision status:	Revision date:	Amendment/s of the document:	Responsible person:
--	19.12.2011	New version	M. Herzog
A	01.06.2012	Correction of remark (page 7)	M. Herzog
B	24.06.2013	"intended use" and "instructions for use" added	M. Herzog

VERIFICATION AND APPROVAL:

issued / revised:		Verification and approval:	
QA / RA		Marketing and Sales	
Date:	24.06.2013	Date:	24.06.2013
Name:	M. Herzog	Name:	Fabian-Alexander Müller
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