Products: 2-part sterile single use syringes with and without needles

Sub chapter: 0010	**Regulatory requirements**
10	Manufacturing site certificated according to ISO 13485: ISO 13485 - Medical devices - Quality management systems
20	ISO 7886-1 - Sterile hypodermic syringes for single use - Part 1: Syringes for manual use ISO 8537 - Sterile single-use syringes, with or without needle, for insulin; valid only for syringes labeled insulin ISO 7864 - Sterile hypodermic needles for single use
30	HSW- Classification of the product according to MDD 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, Suitable for food contact and disposable syringes Luer connector according to ISO 594-1 / DIN EN 20594-1: Conical fittings with a 6% (Luer) taper for syringes, needles and 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 Catheter tip according to drawing, not compatible with Luer / Luer Lock fittings
20	Printing of the barrel according to drawing
30	Lubricant according to ISO 7886-1 resp. ISO 8537 for insulin syringes erucic and/or oleic acid amid max. 0.6% (m/m) of the barrel mass
40	Material and color of two-piece plungers PE-HD (high density polyethylene), color according to drawing
45	for Norm-Ject EVO- syringes: material of O-Ring: Silicone – heat – curing elastomer for Norm-Ject EVO- syringes: plunger material: PE-HD (high density polyethylene), color according to drawing
50	Needles needles according to ISO 7864 - Sterile hypodermic needles for single use; color coding according to ISO 6009 - Hypodermic needles for single use

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 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
20	Dead space of insulin syringe according to ISO 8537 without needle: <= 0.07 ml with attached needle: <= 0.10 ml with fixed 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 5 ml: ±0.2 ml 10 ml: ±0.4 ml 20 ml: ±0.8 ml 30 ml: ±1,2 ml 50 ml: ±2 ml
40	Accuracy of dosage by nominal capacity graduation line according to ISO 8537 for insulin syringes 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 the seal of the plunger and the barrel at min. 88 kPA below atmospheric pressure
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	Two-piece plunger 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)

30	Needles 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	Pyrogene Non-pyrogenic
50	Latex latex free
60	PVC / plasticizers PVC free / plasticizers free
70	Phthalate Phthalate-free
80	BPA Bisphenol A (BPA)-free (free of Polycarbonate)
90	REACH (1907/2006): Does not contain any substances outlined in the SVHC- list.
100	Precontamination < 100 cfu per product
110	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.
120	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
130	Recommended sterilization method during further processing: ethylene oxide other sterilization methods may have influence on mechanical properties, turbidity, discoloration and may result in particles

140	Residual gas analysis according to ISO 10993-7 - Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
150	Silicone Oil produced without the addition of silicone oil lubricants
Sub chapter: 0060	**Packaging**
10	Labeling of primary container according to ISO 7886-1 either 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, note regarding examination of integrity, LOT-No., expiry date, name, trademark, trade name or logo of the manufacturer or supplier Labeling Bulk unsterile & mini 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 Primary container mini-bulk unsterile: Microsnap® bag
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 Labeling mini-bulk unsterile: description of content, nominal capacity, type of nozzle, number, the word "non sterile", LOT-No., name and address of manufacturer or supplier

40	Secondary container standard sterile: Card board box Secondary container mini-bulk: Polybag in corrugated card board covered with polybag foil on the inside transport wrapping
50	Transport wrapping standard sterile: Corrugated card board
60	Packing contents primary container: Standard sterile: one piece per sterile blister pack Mini-bulk unsterile: < 30 mL: 100 pcs per bag 30 mL: 50 pcs per bag 50 mL: 30 pcs per bag 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 50 mL: 500 pcs
70	Packing contents secondary container: Standard sterile: 1 mL - 20 mL: 100 pcs 30 mL: 50 pcs 50 mL: 30 pcs Mini-bulk: 1 mL: 7.000 pcs (70 bags) 2 mL: 6.000 pcs (60 bags) 5 mL: 3.200 pcs (32 bags) 10 mL: 1.900 pcs (19 bags) 20 mL: 1.000 pcs (10 bags) 30 mL: 800 pcs (16 bags) 50 mL: 480 pcs (16 bags)

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: 500 pcs (10 secondary container) 50 mL: 300 pcs (10 secondary container)
90	Storage conditions: Store at room temperature, protect against moisture and sunlight

Remark for bulk packaged syringes:

For bulk packaged unsterile syringes chapter 30, 120 and 140 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.

Precautions:

- 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.

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.

REVISIONS OF DOCUMENT:

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--	13.05.2011	New version	M. Herzog
A	10.02.2012	Sections „intended use“ and „precautions“ added	M. Herzog
B	22.03.2012	Section 0050 / 150 added	M. Herzog
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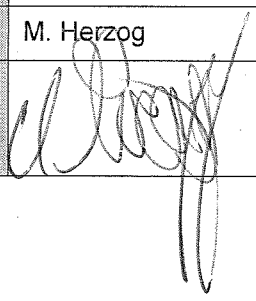
Signature:		Signature: