Materialbezeichnung / Material description	2-part sterile single use syringes with and without needles

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

Design of Single Parts	
40	Material and color of the barrel PP (polypropylene), random copolymer containing a slip agent as lubricant, Suitable for food contact and disposable syringes Luer Slip and Luer Lock connector according to ISO 80369-7: Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications Oral tip: according to drawing, not compatible with Luer / Luer Lock fittings Catheter tip according to drawing, not compatible with Luer / Luer Lock fittings
50	Printing of the barrel according to ISO 7886-1 resp. ISO 8537 for insulin syringes and drawing
60	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
70	Material and color of two-piece plungers PE-HD (high density polyethylene), color according to drawing
80	Needles needles according to ISO 7864 - Sterile hypodermic needles for single use; color coding according to ISO 6009 - Hypodermic needles for single use

Physical qualities	
90	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
100	Dead space of insulin syringe according to ISO 8537 without needle: <= 0.07 ml with by-packed needle: <= 0.10 ml
110	Accuracy of dosage by nominal capacity graduation line acc. to ISO 7886-1 resp. ISO 8537 for insulin syringes 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

120	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
130	Tightness at pressure according to ISO 7886-1, annex D resp. ISO 8537, annex E for insulin syringes The syringe is fluid-tight at following pressures <= 10 ml: 300 kPa > 10 ml: 200 kPa
140	Shelf life, sterile product 5 years

Chemical qualities	
150	Chemical examinations according to ISO 7886-1 resp. ISO 8537 for insulin syringes - limits for extractable metals
160	Chemical examinations according to European Pharmacopoeia section "3.2.8." - Solution - Appearance of solution - Acidity or alkalinity - Absorbance - Reducing substances - Transparency/Opalescence
170	Chemical examinations at needles - Acidity or alkalinity - Heavy metals - Cadmium - Resistance to corrosion

Biological qualities	
180	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)
190	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)
200	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)
210	Pyrogene Non-pyrogenic unique qualification acc. to EP 2.06.08 'Pyrogens' regular inspections acc. to EP 2.06.14 'Bacterial endotoxins' (LAL – Limulus Lysate Amoebocyte)

220	Latex latex free
230	PVC PVC free (free of Polyvinyl chloride)
240	Phthalate Phthalate-free
250	BPA Bisphenol A (BPA)-free (free of Polycarbonate)
260	REACH (1907/2006): Does not contain any substances outlined in the SVHC- list.
270	Precontamination < 100 cfu per product
280	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.
290	Sterilization with ethylenoxide according to EN 556-1 - Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part. 1: Requirements for terminally sterilized medical devices; ISO 11135 - Medical devices - Validation and routine control of ethylene oxide sterilization
300	Recommended sterilization method during further processing: ethylene oxide other sterilization methods may have influence on mechanical properties, turbidity, discoloration and may result in particles
310	Residual gas analysis according to ISO 10993-7 - Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals <= 4 mg EO/device after 24h Note: according to ISO 10993-7 the measurement of ethylene chlorohydrin (ECH) is included. ECH is the reaction product of EO with free chlorine ions. Since the products not made of chlor-containing materials, the test according to ISO 10993-7, Annex C can be omitted.
320	Silicone Oil produced without the addition of silicone oil lubricants

Packaging	
330	Labeling of primary container according to ISO 7886-1 either ISO 8537 for insulin syringes, symbols according to ISO 15223-1
340	Primary container standard sterile according to ISO 11607-1: heat sealed peel-off blister package consisting of composite PP/PA/PE or PA/PE film backed by medical grade paper
350	Labeling of secondary container & transport wrapping according to ISO 7886-1 or ISO 8537 for insulin syringes, symbols according to ISO 15223-1
360	Secondary container standard sterile: Card board box Secondary container bulk non-sterile: PE-bag, transparent, yellow Secondary container mini-bulk: Microsnap® bag

370	Transport wrapping standard sterile:		
	Corrugated card board		
	Transport wrapping bulk non-sterile and mini-bulk:		
	Corrugated card board with inside PE-bag		
380	Packing contents primary container:		
	Standard sterile:	one piece per sterile blister pack	
390	Packing contents secondary container:		
	Standard sterile:	1 mL - 20 mL:	100 pcs
		30 mL:	50 pcs
		50 mL:	30 pcs
	Bulk non-sterile:	1 mL:	3.500 pcs per bag
		2 mL / 3 mL Luer/LL:	3.150 pcs per bag
		2 mL oral:	3.000 pcs per bag
		5 mL Luer/LL:	1.800 pcs per bag
		5 mL oral:	1.500 pcs per bag
		10 mL:	1.000 pcs per bag
		20 mL:	500 pcs per bag
		30 mL:	800 pcs per bag
		50 mL:	500 pcs per bag
	Mini-bulk non-sterile:	< 30 mL:	100 pcs per bag
		30 mL:	50 pcs per bag
		50 mL:	30 pcs per bag
400	Packing contents transport wrapping:		
	Standard sterile:	1 mL:	1.800 pcs (18 secondary containers)
		2 mL:	2.500 pcs (25 secondary containers)
		5 mL:	2.000 pcs (20 secondary containers)
		10 mL:	1.200 pcs (12 secondary containers)
		20 mL:	800 pcs (8 secondary containers)
		30 mL:	500 pcs (10 secondary containers)
		50 mL:	300 pcs (10 secondary containers)
	Bulk non-sterile:	1 mL:	7.000 pcs. (2 bags of each 3.500 pcs)
		2 mL / 3 mL Luer/LL:	6.300 pcs. (2 bags of each 3.150 pcs)
		2 mL oral:	6.000 pcs. (2 bags of each 3.000 pcs)
		5 mL Luer/LL:	3.600 pcs. (2 bags of each 1.800 pcs)
		5 mL oral:	3.000 pcs. (2 bags of each 1.500 pcs)
		10 mL:	2.000 pcs. (2 bags of each 1.000 pcs)
		20 mL:	1.000 pcs. (2 bags of each 500 pcs)
		30 mL:	800 pcs. (1 bag of 800 pcs)
		50 mL:	500 pcs. (1 bag of 500 pcs)
	Mini-bulk non-sterile:	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)
410	Storage conditions:		
	Store at room temperature, protect against moisture and sunlight		

Remark for bulk packaged syringes:
For bulk packaged non-sterile syringes chapters 80, 200, 210, 290 and 310 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 withdrawal of 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.

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

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

The specifications are subject to change without prior notice.

ÄNDERUNGSHISTORIE / AMENDMENT OF DOCUMENT:

Revisionsstand: Revision status:	Änderungs-Datum: Revision date:	Änderung/en: Amendment/s of the document:	Verantwortliche/r: Responsible person:
--	10.01.2019	Neuerstellung	Kerstin Braun
A	26.02.2019	„Remark for bulk packaged syringes" (Seite 5 oben) um Kapitel 210 ergänzt, da Pyrogenfreiheit für Bulkware nicht bestätigt werden kann	Kerstin Braun

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