Materialbezeichnung / Material description	3-part sterile single use syringes 0,5 ml – 30 ml with and without needles

Regulatory Requirements	
10	Manufacturing site certificate 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 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 Regulation (EU) 2017/745 (MDR): Rule 2 of Annex VIII

Design of Single Parts	
50	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
60	Nozzle of the barrel 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 Catheter tip according to drawing, not compatible with Luer / Luer Lock fittings
70	Printing of the barrel according to ISO 7886-1 resp. ISO 8537 for insulin syringes and drawing
80	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
90	Siliconization according to ISO 7886-1 resp. ISO 8537 for insulin undiluted polydimethylsiloxane max. 0,25 mg/cm² of the barrel inside surface
100	Material and color of three-piece plungers 0,5 - 1 ml - PS (polystyrene) or ABS or PP (polypropylene) 2 - 100 ml - PP (polypropylene), homopolymer color according to drawing
110	Material and color of piston polyisoprene rubber, latex free, color according to drawing except 50 ml Luer, 50 ml catheter and 100 ml catheter: TPE
120	Needles needles according to ISO 7864 - Sterile hypodermic needles for single use; color marking according to ISO 6009 - Hypodermic needles for single use
130	Material and color of needle cap PE (high density polyethylene) or PP (poly propylene), color according to drawing
140	Material and color of protective end cap PE (high density polyethylene) or PP (poly propylene), color according to drawing
150	Material and color of needle hub PP (polypropylene), color according to drawing
160	Design of needle tube according to ISO 9626

Physical qualities	
170	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
180	Dead space of insulin syringe according to ISO 8537 without needle: <= 0.07 ml with by-packed needle: <= 0.10 ml with fixed needle: <= 0.01 ml
190	Accuracy of dosage by nominal capacity graduation line acc. 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
200	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
210	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
220	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
230	Shelf life, sterile product 5 years

Chemical qualities	
240	Chemical examinations according to ISO 7886-1 resp. ISO 8537 for insulin syringes - limits for extractable metals
250	Chemical examinations at needles - Acidity or alkalinity - Heavy metals - Cadmium - Resistance to corrosion

Biological qualities	
260	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)
270	Three-piece plunger according to ISO 10993: - cytotoxicity (ISO 10993-5)
280	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)
290	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)
300	Protective cap for cannula according to ISO 10993 - cytotoxicity (ISO 10993-5)
310	Protective cap for plunger according to ISO 10993 - cytotoxicity (ISO 10993-5)
320	Hub according to ISO 10993 - cytotoxicity (ISO 10993-5)
330	Pyrogene Non-pyrogenic unique qualification according to ISO 7886-1 regular inspections according to Chinese Pharmacopoeia, requirement is ⩽20EU/pc.
340	Latex latex free
350	PVC PVC-free (free of Polyvinyl chloride)
360	Phthalate Phthalate-free
370	BPA Bisphenol A (BPA)-free (free of Polycarbonate)
380	REACH (1907/2006) Does not contain any substances outlined in the SVHC-list.
390	Precontamination < 100 cfu per product
400	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.
410	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
420	Recommended sterilization during further processing: ethylenoxide other sterilization methods may have influence on mechanical properties, turbidity, discoloration and particles
430	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.

Packaging	
450	Labeling of primary container according to ISO 7886-1, respectively ISO 7886-2 (for syringes for use with power-driven syringe pumps) or ISO 8537 (for insulin syringes); symbols according to ISO 15223-1
460	Primary container standard sterile according to ISO 11607-1: Single blister: heat sealed peel-off blister package consisting of composite PP/PA/PE or PA/PE film backed by medical grade paper PP/PE Insulin syringes PB (pharmacy bag): PP/PE compound bag
470	Labeling of secondary container & transport wrapping according to ISO 7886-1, respectively ISO 7886-2 (for syringes for use with power-driven syringe pumps) or ISO 8537 (for insulin syringes); symbols according to ISO 15223-1
480	Secondary container standard sterile: Card board box Secondary container bulk non-sterile: PE-bag, transparent 1 ml LDS: PE-bag, transparent, in card board box
490	Transport wrapping standard sterile: Corrugated card board Transport wrapping bulk non-sterile: Corrugated card board with inside PE-bag
500	Packing contents primary container: Standard sterile: one piece per sterile blister pack Insulin syringes PB: ten pieces per polybag
510	Packing contents secondary container: Standard sterile: 1 mL - 20 mL: 100 pcs 30 mL: 50 pcs Bulk non-sterile: 1 mL: 4.450 pcs per bag 1 mL LDS 4.450 pcs. per bag 3 mL: 4.000 pcs per bag 5 mL: 2.800 pcs per bag 10 mL: 1.700 pcs per bag 20 mL: 1.000 pcs per bag 30 mL: 800 pcs per bag
520	Packing contents transport wrapping: Standard sterile: 1 mL: 2.000 pcs (20 secondary containers) 1 mL LDS: 2.000 pcs. (20 secondary containers)

		1 mL fixed needle:	2.000 pcs. (20 secondary containers)
		2 mL:	1.200 pcs. (12 secondary containers)
		3 mL:	1.200 pcs. (12 secondary containers)
		5 mL:	1.200 pcs. (12 secondary containers)
		10 mL:	1.200 pcs (12 secondary containers)
		20 mL:	600 pcs (6 secondary containers)
		30 mL:	500 pcs (5 secondary containers)
	Bulk non-sterile:	1 mL:	4.450 pcs.
		1 mL LDS:	4.450 pcs.
		3 mL:	4.000 pcs.
		5 mL:	2.800 pcs.
		10 mL:	1.700 pcs.
		20 mL:	1.000 pcs.
		30 mL:	800 pcs.
	Storage conditions: Store at room temperature, protect against moisture and sunlight		

Remark for bulk packaged syringes:
For bulk packaged non-sterile syringes chapters 120 – 160, 260, 300 – 330, 420 and 440 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.

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