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Materialbezeichnung / Material description	sterile single use hypodermic needles

Regulatorische Anforderungen		Regulatory Requirements
10	Manufacturing site certificated according to ISO 13485: ISO 13485 - Medical devices - Quality management systems	
20	ISO 7864 - Sterile hypodermic needles for single use	
30	HSW- Classification of the product according to 93/42/EWG: IIa / Rule 6	

Design der Einzelteile		Design of Single Parts
40	Material of the needle Stainless steel acc. to ISO 9626 Diameter tolerances according to ISO 9626	
50	Material of the hub Polypropylene 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 Color coding of hub according to ISO 6009	
60	Material of the protector: Polypropylene	
70	Siliconization according to ISO 7864: Undiluted polydimethylsiloxane, max. 0.25 mg/cm² on the surface of the needle	

Physikalische Eigenschaften		Physical qualities
80	Grinding angles: According to ISO 7864 First angle: 11° +/- 2° for standard bevel 15° +/- 2°: for short bevel	
90	Needle length tolerances according to ISO 7864: < 25 mm: + 1 mm / - 2 mm 25 – 39 mm: + 1,5 mm / - 2,5 mm 40 mm: 0 / - 4 mm > 40 mm: + 1,5 mm / -2,5 mm	
100	Connection strength between needle hub and cannula: According to ISO 7864	
110	Shelf life, sterile product 5 years	

Chemische Eigenschaften		Chemical qualities
120	Chemical examinations according to ISO 7864: - limits for acidity or alkalinity - limits for extractable metals	

Biologische Eigenschaften		Biological qualities
130	needle according to ISO 10993-1: - haemolysis (ISO 10993-4) - cytotoxicity (ISO 10993-5) - irritation (ISO 10993-10) - sensitization (ISO 10993-10)	

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	- systemic toxicity (ISO 10993-11)
140	Pyrogene Non-pyrogenic
150	Latex latex free
160	PVC / plasticizers free of PVC and its phthalates / plasticizers free
170	Bisphenol-A Bisphenol-A free
180	REACH (1907/2006): Does not contain any substances outlined in the SVHC- list.
190	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.
200	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
210	Recommended sterilization during further processing ethylenoxide other sterilization methods may have influence on mechanical properties, turbidity, discoloration or may result in particles
220	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.

Verpackung	Packaging
230	Labeling of primary container according to ISO 7864, symbols according to ISO 15223-1 Colour coding acc ISO 6009
240	Primary container 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 Colour coding acc ISO 6009
250	Labeling of secondary container & transport wrapping according to ISO 7864, symbols according to ISO 15223-1 Colour coding acc ISO 6009
260	Secondary container cardboard box contents: 100 pcs needles
270	Transport wrapping corrugated cardboard box contents: needle length units ≤ 40 mm: 4.000 pcs needles / 40 boxes > 40 mm and < 70 mm: 3.000 pcs needles / 30 boxes ≥ 70 mm and ≤ 120 mm: 2.000 pcs needles / 20 boxes

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280	Pallet contents: needle length units ≤ 40 mm: 200.000 pcs needles / 2.000 boxes / 50 transport wrappings > 40 mm und ≤ 50 mm: 180.000 pcs needles / 1.800 boxes / 60 transport wrappings 60 mm 102.000 pcs. needles / 1.020 boxes / 34 transport wrappings ≥ 70 mm and ≤ 120 mm: 60.000 pcs needles / 600 boxes / 30 transport wrappings
290	Storage conditions: Store in original, unopened packing, in closed premises at room temperature Keep dry and protect against moisture and sunlight

Remark for bulk packaged needles:
Bulk packaged unsterile needles are not considered as medical devices. Therefore, chapters 140 and 200 - 280 do not apply for bulk unsterile needles.

Intended use:
The single-use hypodermic needles 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 fluids from the body or vial

Precautions:
- If the packaging is damaged or opened the product should not be used due to potential impairment of the sterility conditions.
- Connect the hypodermic needle with an adequate medical devices (e. g. syringe).
- Make sure the needle is secured safely, then carefully remove the protector.
- Do not recap. Dispose the needle in a sharps container.
- Once used do not re-use or re-sterilize.

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

Further processing of the products
The customer is responsible for any further processing of the delivered products.

The specifications are subject to change without prior notice.

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A	10.10.2019	First angle – short bevel changed from 17° ±2° to 15°±2°	Michel Biesinger

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