Specification

Name:	SOFT-JECT®	**Creator:**	QPP-Frau Schreiber
No. of specification:	SPSOFT / SP	**Valid from:**	2017-12-06

Release of specification:

Material No.:	Name:	Drawing No.:
8300005761	3 ML HSW SOFT-JECT®	3-0240
8300005762	3 ML HSW SOFT-JECT®LUER LOCK	3-2300
8300006797	3 ML HSW SOFT-JECT®BK 0,80X40/21GX11/2	3-0240/0,80-X15
8300006799	3 ML HSW SOFT-JECT®BK 0,60X30/23GX11/4	3-0240/0,60-X15
8300006800	3 ML HSW SOFT-JECT®BK 0,60X25/23GX1	3-0240/0,60-X15
8300008287	2 ML (2,5 ML) HSW SOFT®LL BK 0,60X30	2-2300/0,60-X15
8300009511	3 ML HSW SOFT-JECT ISRAEL	3-2850
8300013524	20 ML SOFT-JECT®ZENTR. BK 20GX11/2	20-0650/0,90-X15
8300016323	20 ML HSW SOFT-JECT® LL BK 18GX11/2	20-2300/1,20-X15
8300020439	5 ML SOFT-JECT®BK 0,90X40/20GX11/2	5-0240/0,90-X15
8300021298	5 ML HSW SOFT-JECT® LL BK 21GX11/2	5-2300/0,80-X15
8300034773	2 ML HSW SOFT-JECT®LUER LOCK NEUTRAL	2-3760
8300036423	1 ML HSW SOFT-JECT®INSULIN 40IU	1-0190
5010-100V0	1 ML SOFT-JECT INS. 40IU VET	1-0190
5010-200V0	1 ML SOFT-JECT TUBERKULIN	1-0130
5010-A00V0	1 ML SOFT-JECT INS. 100IU	1-0110
50127100V0	1 ML SOFT-JECT INS. 40 IU BK 27GX1/2	1-0190/0,40-X15
50127200V0	1 ML SOFT-JECT TUBERK. BK 27GX1/2	1-0130/0,40-X15
50127A00V0	1 ML SOFT INS. 100 IU BK 0,40X12	1-0110/0,40-X15
5012A200V0	1 ML SOFT-JECT®TBC BK 0,45X12/26GX1/2	1-0130/0,45-X15
5012B200V0	1 ML SOFT-JECT TBC BK 25GX5/8	1-0130/0,50-X15
5012BA00V0	1 ML SOFT-JECT INS 100IU BK 25GX5/8	1-0110/0,50-X15
5020-000V0	2 ML HSW SOFT-JECT®	2-0240
5022D000V0	2 ML SOFT-JECT®BK 0,80X40/21GX11/2	2-0240/0,80-X15
5022L000V0	2 ML SOFT-JECT®BK 0,60X30/23GX11/4	2-0240/0,60-X15
5022S000V0	2 ML HSW SOFT-JECT®BK 0,60X25/23GX1	2-0240/0,60-X15
5040-X00V0	2,5 ML SOFT-JECT LUER LOCK	2-2300
50424000V0	2 ML (2,5 ML) SOFT-JECT®BK 22GX1	2-0240/0,70-X15
5042B000V0	2 ML (2,5 ML) SOFT-JECT®BK 25GX5/8	2-0240/0,50-X15
5042G000V0	2 ML (2,5 ML) SOFT-JECT®BK 22GX3/4	2-0240/0,70-X15
5042H000V0	2 ML (2,5 ML) SOFT-JECT®BK 20GX11/2	2-0240/0,90-X15
5042I000V0	2 ML (2,5 ML) SOFT-JECT®BK 20GX1	2-0240/0,90-X15
5050-000V0	5 ML HSW SOFT-JECT®	5-0240
5050-000VZ	5 ML HSW SOFT-JECT®CENTRIC	5-0650
5050-X00V0	5 ML SOFT-JECT LUER LOCK	5-2300
5052D000V0	5 ML SOFT-JECT®BK 0,80X40/21GX11/2	5-0240/0,80-X15
5052K000V0	5 ML SOFT-JECT BK. 0,70X30	5-0240/0,70-X15
5052L000VZ	5 ML SOFT-JECT ZENTR. BK 23GX11/4	5-0650/0,60-X15
5052S000V0	5 ML HSW SOFT-JECT®BK 0,60X25/23GX1	5-0240/0,60-X15
5052Z000V0	5 ML SOFT-JECT®BK 1,20X40/18GX11/2	5-0240/1,20-X15
5100-000V0	10 ML (12 ML) SOFT-JECT	10-0240
5100-000VZ	10 ML (12 ML) SOFT-JECT ZENTRISCH	10-0650

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5100-X00V0	10 ML (12 ML) SOFT-JECT LUER LOCK	10-2300
5102D000V0	10 ML (12 ML) SOFT-JECT BK 21GX11/2	10-0240/0,80-X15
5102H000V0	10 ML (12 ML) SOFT-JECT BK 20GX11/2	10-0240/0,90-X15
5102Z000V0	10 ML (12 ML) SOFT BK 1,20X40/18GX11/2	10-0240/1,20-X15
5200-000V0	20 ML SOFT-JECT	20-0240
5200-X00V0	20 ML SOFT-JECT LUER LOCK	20-2300
5202D000V0	20 ML SOFT-JECT BK 21GX11/2	20-0240/0,80-X15
5202H000V0	20 ML SOFT-JECT BK 20GX11/2	20-0240/0,90-X15
5202Z000V0	20 ML SOFT-JECT BK 18GX11/2	20-0240/1,20-X15
5300-000D0	30ML HSW SOFT-JECT®	30-0240
5300-X00D0	30ML HSW SOFT-JECT® LUER LOCK	30-2300

	Sector / Name / Signature
Technical part	Signed by original
Quality Inspection Planning	Signed by original
Customer Service	Signed by original
Agreement customer	

SOFT-JECT®
3-tlg. Einmalspritze ohne Kanüle / mit beigelegter Kanüle (bK)
3-part single-use syringe without needle / with by-packed needle (bK)

_____
Freigabe Kunde/Release Customer:

_____ _____
Datum/Date Unterschrift/Signature

Additional regulations

This specification provides a basis for the requirements of the syringes and their packaging.
Additional requirements must be communicated and agreed in writing with Henke-Sass, Wolf GmbH.

Further processing of the syringes
The customer himself is responsible for every way of further processing of the delivered syringes.

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Name:	SOFT-JECT®	**Creator:**	QPP-Frau Schreiber
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Modification history

Change no.: 500000120059 valid from: 2017-12-06

SPSOFT/SP

Geändert von: HC-PM-DE01 M. Schreiber
Modified by:

Plangruppe 0010 Regulatorische Anforderungen, Merkmal 10
Planning group 0010 Regulatory requirements, Characteristic feature 10
Entfall ISO 9001 / deletion of ISO 9001

Name:	SOFT-JECT®	**Creator:**	QPP-Frau Schreiber
No. of specification:	SPSOFT / SP	**Valid from:**	2017-12-06

Planning group
Characteristic feature / text

Planning group 0010	**Regulatorische Anforderungen** **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
30	ISO 7886-2 - Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps valid only for syringes with Luer Lock connection
40	ISO 8537 - Sterile single-use syringes, with or without needle, for insulin valid only for insulin syringes
50	Classification of the product according to 93/42/EWG has to occur from the party responsible for manufacture
60	Intended use Injection: The single-use syringes were used for intravenous, intramuscular, subcutaneous, intracutaneous and intraarterial injection of liquids or diluted drugs in combination with an adequate medical device. Extraction of body fluids: The body fluids were extracted per aspiration with an adequate medical device, e.g. blood withdrawal with a needle for laboratory tests. Mixing of drugs and drugs with infusion solutions: In accordance with the therapy plan, drugs were mixed or admixed to an infusion solution.
70	MSDS-Declaration The products do not fall under the regulation 29 CFR § 1910.1200 and the European Directives 67/548/EEC and 88/379/EEC. The products do not fulfill the requirements for raw materials and formulations as per the regulations and directives above and therefore these products are exempt from the provision to be provided with a material safety data sheet.

Planning group 0020	**Ausführung Einzelteile** **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 - 30 ml - PP (polypropylene), homopolymer color according to drawing

Effective

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Planning group
Characteristic feature / text

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

Planning group 0030	**Physikalische Eigenschaften** **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
20	Dead space of insulin syringe according to ISO 8537 without needle <= 0.07 ml with mounted 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 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
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	slipping test product
60	removal force of the plunger out of the barrel the plunger should not be easily withdraw completely from the barrel
70	liquid tightness of product leakages between plunger and barrel are not acceptable during injection and aspiration with water
80	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
90	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
100	Strength of connections between piston / plunger according to ISO 7886-1, annex B resp. ISO 8537, annex B for insulin syringes min. 88 kPA below atmospheric pressure

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HENKE SASS WOLF

Specification

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Planning group
Characteristic feature / text

110	Shelf life, sterile product 5 years
Planning group 0040	**Chemische Eigenschafte Chemical qualities**
10	Chemical examinations according to ISO 7886-1 resp. ISO 8537 for insulin syringes - 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
30	Chemical examinations at needles - Acidity or alkalinity - Heavy metals - Cadmium - Resistance to corrosion
Planning group 0050	**Biologische Eigenschaften Biological qualities**
10	Barrel according to ISO 10993 fulfilled demands: - 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 fulfilled demands: - cytotoxicity (ISO 10993-5)
30	Piston according to ISO 10993 fulfilled demands: - haemolysis (ISO 10993-4) - cytotoxicity (ISO 10993-5) - irritation (ISO 10993-10) - sensitization (ISO 10993-10) - systemic toxicity (ISO 10993-11)

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Planning group
Characteristic feature / text

40	Needles according to ISO 10993 fulfilled demands: - haemolysis (ISO 10993-4) - cytotoxicity (ISO 10993-5) - irritation (ISO 10993-10) - sensitization (ISO 10993-10) - systemic toxicity (ISO 10993-11)
50	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)
60	Latex latex free
70	PVC PVC-free (free of Poly(vinyl chloride))
80	Phthalate Phthalate-free
90	REACH does not contain products according to SVHC-list
100	BPA Bisphenol A (BPA)-free (free of Polycarbonate)
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 "Minimising 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 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
130	Recommended sterilization during further processing ethylenoxide other sterilization methods may have influence on mechanical properties, turbidity, discoloration and particles
140	Residual gas analysis according to ISO 10993-7 - Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals <= 4 mg EO/device after 24 h 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.

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Planning group
Characteristic feature / text

Planning group 0060	**Verpackung** **Packing**
10	Labeling of primary container according to ISO 7886-1 either ISO 8537 for insulin syringes, symbols according EN 980 text: 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
20	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
30	Labeling of secondary container, transport wrapping according to ISO 7886-1 either ISO 8537 for insulin syringes, symbols according to EN 980 text: 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 1 - 20 ml cardboard box contents: 100 syringes 30 ml corrugated cardboard box contents: 60 syringes
50	Transport wrapping corrugated cardboard box contents: size secondary container 1 ml 18 2 ml 25 3 ml 24 5 ml 20 10 ml 12 20 ml 8 30 ml 10
60	Pallet contents: sizes transport wrappings 1 ml 30 2 ml 20 3 ml 20 5 ml 16 10 ml 18 20 ml 16 30 ml 15
70	Storage conditions store at a dry place and protect against sunlight

Effective

- End Product Specification -

Title: SPSOFT /SP - SOFT-JECT® Initiator: Martina ? Schreiber

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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