



# Product Specifications for HSW SOFT-JECT®

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Document number:

PSP-SOFT-JECT

Revision status: B

Revision date:

24.06.2013

**Products:** 3-part sterile single use syringes with and without needles

| Sub chapter: 0010 |  | Regulatory requirements                                                                                                                                                                                                                                                                                                                           |
|-------------------|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10                |  | Manufacturing site certificated according to ISO 13485 either ISO 9001<br>ISO 13485 - Medical devices - Quality management systems;<br>ISO 9001 - Quality management systems                                                                                                                                                                      |
| 20                |  | ISO 7886-1 - Sterile hypodermic syringes for single use - Part 1: Syringes for manual use<br>ISO 7886-2 - Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps<br>ISO 7864 – Sterile hypodermic needles for single use                                                                           |
| 30                |  | ISO 8537 – Sterile single-use syringes, with or without needle, for insulin<br>valid only for insulin syringes                                                                                                                                                                                                                                    |
| 40                |  | Classification of the product according to 93/42/EWG<br>Ism / Rule 2 for syringes w/o needles<br>IIa / Rule 2 for syringes for use with power-driven syringe pumps<br>IIa / Rule 6 for syringes with needles                                                                                                                                      |
| Sub chapter: 0020 |  | Design of single parts                                                                                                                                                                                                                                                                                                                            |
| 10                |  | Material and color of the barrel<br>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<br>Luer according to ISO 594-1 / DIN EN 20594-1<br>Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment;<br>Luer Lock according to ISO 594-2 / DIN EN 1707<br>Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings |
| 30                |  | Printing of the barrel<br>according to drawing                                                                                                                                                                                                                                                                                                    |
| 40                |  | Lubricant according to ISO 7886-1 resp. ISO 8537 for insulin syringes<br>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<br>undiluted polydimethylsiloxane max. 0,25 mg/cm <sup>2</sup> of the barrel inside surface                                                                                                                                                                                     |



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|                                                  |                                                                                                                                                                                                                                          |
|--------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 60                                               | Material and color of three-piece plungers<br>0,5 - 1 ml - PS (polystyrene)<br>2 - 100 ml - PP (polypropylene), homopolymer<br>color according to drawing                                                                                |
| 70                                               | Material and color of piston<br>polyisoprene rubber, latex free, color according to drawing                                                                                                                                              |
| 80                                               | Needles<br>needles according to ISO 7864 - Sterile hypodermic needles for single use;<br>color marking according to ISO 6009 - Hypodermic needles for single use                                                                         |
| 90                                               | Material and color of needle cap<br>PE (high density polyethylene), color according to drawing                                                                                                                                           |
| 100                                              | Material and color of protective end cap<br>PE (high density polyethylene), color according to drawing                                                                                                                                   |
| 110                                              | Material and color of hub<br>PP (polypropylene), color according to drawing                                                                                                                                                              |
| 120                                              | Design of needle tube<br>according to ISO 9626                                                                                                                                                                                           |
| <b>Sub chapter: 0030      Physical qualities</b> |                                                                                                                                                                                                                                          |
| 10                                               | Dead space of syringe according to ISO 7886-1<br>1 ml: <= 0.07 ml<br>2 ml: <= 0.07 ml<br>3 ml: <= 0,07 ml<br>5 ml: <= 0.075 ml<br>10 ml: <= 0.10 ml<br>20 ml: <= 0.15 ml<br>30 ml: <= 0.17 ml<br>50 ml: <= 0.20 ml<br>100 ml: <= 0.20 ml |
| 20                                               | Dead space of insulin syringe according to ISO 8537<br>without needle: <= 0.07 ml<br>with attached needle: <= 0.10 ml<br>with jointed needle: <= 0.01 ml                                                                                 |



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|                                                  |                                                                                                                                                                                                                                                                                          |
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| 30                                               | Accuracy of dosage by nominal capacity graduation line according to ISO 7886-1<br>1 ml: $\pm 0.05$ ml<br>2 ml: $\pm 0.1$ ml<br>3 ml: $\pm 0,15$ ml<br>5 ml: $\pm 0.2$ ml<br>10 ml: $\pm 0.4$ ml<br>20 ml: $\pm 0.8$ ml<br>30 ml: $\pm 1,2$ ml<br>50 ml: $\pm 2$ ml<br>100 ml: $\pm 4$ ml |
| 40                                               | Accuracy of dosage by nominal capacity graduation line according to ISO 8537 for insulin syringes<br>0,5 ml: $\pm 0,025$ ml<br>1 ml: $\pm 0.05$ ml                                                                                                                                       |
| 50                                               | Tightness at vacuum according to ISO 7886-1, annex B resp. ISO 8537, annex B for insulin syringes<br>The syringe is air-tight between piston and barrel at min. 88 kPa below atmospheric pressure, the piston remains at the plunger                                                     |
| 60                                               | Tightness at pressure according to ISO 7886-1, annex D resp. ISO 8537, annex F for insulin syringes<br>The syringe is fluid-tight at following pressures<br>$\leq 10$ ml: 300 kPa<br>$> 10$ ml: 200 kPa                                                                                  |
| 70                                               | Shelf life, sterile product<br>5 years                                                                                                                                                                                                                                                   |
|                                                  |                                                                                                                                                                                                                                                                                          |
| <b>Sub chapter: 0040      Chemical qualities</b> |                                                                                                                                                                                                                                                                                          |
| 10                                               | Chemical examinations according to ISO 7886-1 resp. ISO 8537 for insulin syringes<br>- limits for acidity or alkalinity<br>- limits for extractable metals                                                                                                                               |



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|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 20                                                 | Chemical examinations according to European Pharmacopoeia section "3.2.8." <ul style="list-style-type: none"><li>- Solution</li><li>- Appearance of solution</li><li>- Acidity or alkalinity</li><li>- Silicone oil</li><li>- Absorbance</li><li>- Reducing substances</li><li>- Transparency/Opalescence</li></ul> |
| 30                                                 | Chemical examinations at needles <ul style="list-style-type: none"><li>- Acidity or alkalinity</li><li>- Heavy metals</li><li>- Cadmium</li><li>- Resistance to corrosion</li></ul>                                                                                                                                 |
| <b>Sub chapter: 0050      Biological qualities</b> |                                                                                                                                                                                                                                                                                                                     |
| 10                                                 | Barrel according to ISO 10993: <ul style="list-style-type: none"><li>- haemolysis (ISO 10993-4)</li><li>- cytotoxicity (ISO 10993-5)</li><li>- irritation (ISO 10993-10)</li><li>- sensitization (ISO 10993-10)</li><li>- systemic toxicity (ISO 10993-11)</li></ul>                                                |
| 20                                                 | Three-piece plunger according to ISO 10993: <ul style="list-style-type: none"><li>- cytotoxicity (ISO 10993-5)</li></ul>                                                                                                                                                                                            |
| 30                                                 | Piston according to ISO 10993: <ul style="list-style-type: none"><li>- haemolysis (ISO 10993-4)</li><li>- cytotoxicity (ISO 10993-5)</li><li>- irritation (ISO 10993-10)</li><li>- sensitization (ISO 10993-10)</li><li>- systemic toxicity (ISO 10993-11)</li></ul>                                                |



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|     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 40  | Needle according to ISO 10993<br>- haemolysis (ISO 10993-4)<br>- cytotoxicity (ISO 10993-5)<br>- irritation (ISO 10993-10)<br>- sensitization (ISO 10993-10)<br>- systemic toxicity (ISO 10993-11)                                                                                                                                                                                                                                                                                                                                                                                   |
| 50  | Protective cap for cannula according to ISO 10993<br>- cytotoxicity (ISO 10993-5)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 60  | Protective cap for plunger according to ISO 10993<br>- cytotoxicity (ISO 10993-5)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 70  | Hub according to ISO 10993<br>- cytotoxicity (ISO 10993-5)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 80  | Pyrogene<br>Non-pyrogenic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 90  | Latex<br>latex free                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 100 | PVC / plasticizers<br>PVC free / plasticizers free                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 110 | Phthalate<br>Phthalate-free                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 120 | BPA<br>Bisphenol A (BPA)-free (free of Polycarbonate)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 130 | REACH (1907/2006)<br>Does not contain any substances outlined in the SVHC-list.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 140 | Precontamination<br>< 100 cfu per product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 150 | BSE / TSE<br>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 Spongiform Encephalopathy Agents via Medicinal Products" are considered to be effective TSE inactivation processes. |



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|                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 160                                     | Sterilization with ethylenoxide according to<br>EN 550 - Sterilization of medical devices; Validation and routine control of ethylene oxide sterilization;<br>ISO 11135 - Medical devices - Validation and routine control of ethylene oxide sterilization                                                                                                                                                                                                                                                                                          |
| 170                                     | Recommended sterilization during further processing<br>ethylenoxide<br>other sterilization methods may have influence on mechanical properties, turbidity, discoloration and particles                                                                                                                                                                                                                                                                                                                                                              |
| 180                                     | Residual gas analysis<br>according to ISO 10993-7 - Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Sub chapter: 0060      Packaging</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 10                                      | Labeling of primary container according to ISO 7886-1 or ISO 8537 for insulin syringes, symbols according EN 980:<br>Labeling Standard sterile:<br>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<br>Labeling bulk unsterile:<br>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:<br>heat sealed peel-off blister package consisting of composite PP/PA/PE or PA/PE film backed by medical grade paper<br>Primary container according to ISO 11607-1<br>Primary container bulk unsterile:<br>Polybag in corrugated card board covered with polybag foil on the inside transport wrapping                                                                                                                                                                                                          |
| 30                                      | Labeling of secondary container & transport wrapping according to ISO 7886-1 or ISO 8537 for insulin syringes, symbols according to EN 980:<br>Labeling Standard sterile:<br>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 standard sterile:<br>cardboard box                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |



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|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 50 | Transport wrapping standard sterile:<br>Corrugated cardboard box                                                                                                                                                                                                                                                                                                                                                 |
| 60 | Packing contents primary container:<br>Standard sterile: one piece per sterile blister pack<br>Bulk unsterile:<br>1 mL: 7.000 pcs per transport wrapping<br>2 mL: 6.300 pcs<br>5 mL: 3.600 pcs<br>10 mL: 2.000 pcs<br>20 mL: 1.000 pcs<br>30 mL: 800 pcs                                                                                                                                                         |
| 70 | Packing contents secondary container:<br>Standard sterile:<br>1 mL - 20 mL: 100 pcs<br>30 mL: 60 pcs<br>50 mL: 50 pcs<br>100mL: 30 pcs                                                                                                                                                                                                                                                                           |
| 80 | Packing contents transport wrapping standard sterile:<br>1 mL: 1.800 pcs (18 secondary container)<br>2 mL: 2.500 pcs (25 secondary container)<br>5 mL: 2.000 pcs (20 secondary container)<br>10 mL: 1.200 pcs (12 secondary container)<br>20 mL: 800 pcs (8 secondary container)<br>30 mL: 600 pcs (10 secondary container)<br>50 mL: 300 pcs (6 secondary container)<br>100 mL: 180 pcs (6 secondary container) |
| 90 | Storage conditions:<br>Store at room temperature, protect against moisture and sunlight                                                                                                                                                                                                                                                                                                                          |

**Remark for bulk packaged syringes:**

Bulk packaged unsterile syringes are not considered as medical devices. Sections: 80, 160, 170 and 180 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.



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## Instructions for use:

- 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:

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## **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**

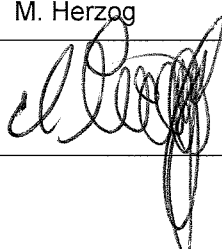
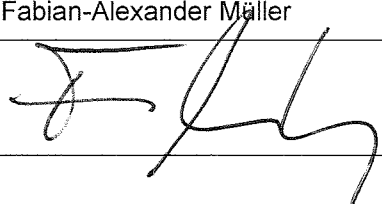
The customer himself is responsible for each way of further processing of the delivered needles.

*The specifications are subject to change without prior notice.*

## **REVISIONS OF DOCUMENT:**

| Revision status: | Revision date: | Amendment/s of the document                     | Responsible person: |
|------------------|----------------|-------------------------------------------------|---------------------|
| --               | 19.12.2011     | New version                                     | M. Herzog           |
| A                | 01.06.2012     | Correction of remark (page 7)                   | M. Herzog           |
| B                | 24.06.2013     | "intended use" and "instructions for use" added | M. Herzog           |

## **VERIFICATION AND APPROVAL:**

| issued / revised: |                                                                                     | Verification and approval: |                                                                                       |
|-------------------|-------------------------------------------------------------------------------------|----------------------------|---------------------------------------------------------------------------------------|
| QA / RA           |                                                                                     | Marketing and Sales        |                                                                                       |
| Date:             | 24.06.2013                                                                          | Date:                      | 24.06.2013                                                                            |
| Name:             | M. Herzog                                                                           | Name:                      | Fabian-Alexander Müller                                                               |
| Signature:        |  | Signature:                 |  |

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