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1 Scope

The Product specification applies to the following products:

Global

Article No.	Product Name	Designation	Drawing
4606027V	Injekt® Luer Solo	INJEKT 2 ML	2-1390
4606027V-03	Injekt® Luer Solo	INJEKT 2 ML-AP	2-1390
4606051V	Injekt® Luer Solo	INJEKT 5 ML	5-1390
4606051V-03	Injekt® Luer Solo	INJEKT 5 ML-AP	5-1390
4606108V	Injekt® Luer Solo	INJEKT 10 ML	10-1390
4606108V-03	Injekt® Luer Solo	INJEKT 10 ML-AP	10-1390
4606205V	Injekt® Luer Solo	INJEKT 20 ML	20-1390
4606205V-03	Injekt® Luer Solo	INJEKT 20 ML-AP	20-1390
4606701V	Injekt® Luer Lock Solo	INJEKT 2 ML LL	2-1430
4606710V	Injekt® Luer Lock Solo	INJEKT 5 ML LL	5-1430
4606728V	Injekt® Luer Lock Solo	INJEKT 10 ML LL	10-1430
4606736V	Injekt® Luer Lock Solo	INJEKT 20 ML LL	20-1430
4645022C	Injekt® Luer Duo	INJEKT 2 ML DUO 23GX1 1/4" KYRILLISCH	2-1390/ 0,60-X15
4645022V	Injekt® Luer Duo	INJEKT 2 ML DUO 23GX1 1/4"	2-1390/ 0,60-X15
4645023-03	Injekt® Luer Duo	INJEKT 5 ML DUO 23GX1/0,60X25-AP	5-1390/ 0,60-X15
4645024-03	Injekt® Luer Duo	INJEKT 5 ML DUO 24GX1/0,55X25-AP	5-1390/ 0,55-X15
4645057C	Injekt® Luer Duo	INJEKT 5 ML DUO 22GX1 1/4"KYRILLISCH	5-1390/ 0,70-X15
4645057V	Injekt® Luer Duo	INJEKT 5 ML DUO 22GX1 1/4"	5-1390/ 0,70-X15
4645103C	Injekt® Luer Duo	INJEKT 10 ML DUO 21GX1 1/2" KYRILLISCH	10-1390/ 0,80-X15
4645103V	Injekt® Luer Duo	INJEKT 10 ML DUO 21GX1 1/2"	10-1390/ 0,80-X15
4645200C	Injekt® Luer Duo	INJEKT 20 ML DUO 21GX1 1/2" KYRILLISCH	20-1390/ 0,80-X15
4645200V	Injekt® Luer Duo	INJEKT 20 ML DUO 21GX1 1/2"	20-1390/ 0,80-X15
4645200V-03	Injekt® Luer Duo	INJEKT 20 ML DUO 21GX1 1/2"-AP	20-1390/ 0,80-X15
4647240-03	Injekt® Luer Duo	INJEKT 2 ML DUO 24GX1/0,55X25-AP	2-1390/ 0,55-X15
9166017V	Injekt®-F Luer Solo	INJEKT 1 ML FEINDOSIERUNG	1-1320

Effective

Article No.	Product Name	Designation	Drawing
9166033V	Injekt®-F Luer Duo	INJEKT 1 ML FEINDOSIERUNG DUO 25GX5/8"	1-1320/ 0,50-X15
9166106V	Injekt®-H Luer Solo	INJEKT 1 ML HEPARIN 10.000IE	1-1340
9166254V	Injekt®-H Luer Solo	INJEKT 1 ML HEPARIN 25.000IE	1-1330

Local

4645021-03	Injekt® Luer Duo	INJEKT 10 ML DUO 21GX1/0,80X25-AP	10-1390/ 0,80-X15
4645065C	Injekt® Luer Duo	INJEKT 5 ML DUO 21GX1 1/2"KYRILLISCH	5-1390/ 0,80-X15
4647220	Injekt® Luer Duo	INJEKT 2 ML DUO 23GX1"	2-1390/ 0,60-X15
9166203V	Injekt®-H Luer Solo	INJEKT 1 ML HEP INNOHEP 20.000 ANTI-XA	1-1460
9166297	Injekt®-H Luer Duo	INJEKT 1 ML HEPA 25.000IE DUO 26GX1/2"	1-1330/ 0,45-X15

Global, without CE-mark

4606027V-02	Injekt™ Syringe Luer Slip	INJEKT 2 ML US	2-3230
4606051V-02	Injekt™ Syringe Luer Slip	INJEKT 5 ML US	5-3230
4606108V-02	Injekt™ Syringe Luer Slip	INJEKT 10 ML US	10-3230
4606205V-02	Injekt™ Syringe Luer Slip	INJEKT 20 ML US	20-3230
4606701V-02	Injekt™ Syringe Luer Lock	INJEKT 2 ML LL US	2-3240
4606710V-02	Injekt™ Syringe Luer Lock	INJEKT 5 ML LL US	5-3240
4606728V-02	Injekt™ Syringe Luer Lock	INJEKT 10 ML LL US	10-3240
4606736V-02	Injekt™ Syringe Luer Lock	INJEKT 20 ML LL US	20-3240
4645022V-02	Injekt™ Syringe Luer Slip	INJEKT 2 ML DUO 23GX1 1/4" US	2-3230/ 0,60-X15
4645057V-02	Injekt™ Syringe Luer Slip	INJEKT 5 ML DUO 22GX1 1/4" US	5-3230/ 0,70-X15
4645103V-02	Injekt™ Syringe Luer Slip	INJEKT 10 ML DUO 21GX1 1/2" US	10-3230/ 0,80-X15

Effective

Article No.	Product Name	Designation	Drawing
4645200V-02	Injekt™ Syringe Luer Slip	INJEKT 20 ML DUO 21GX1 1/2" US	20-3230/ 0,80-X15
9166017V-02	Injekt™ Syringe Luer Slip	INJEKT 1 ML LS US	1-3220
9166033V-02	Injekt™ Syringe Luer Slip	INJEKT 1 ML F LS DUO 25GX5/8 US	1-3220/ 0,50-X15

Customized Label - OEM

4602200	Amefa Luer Solo	AMEFA 2 ML 2-TLG	2-0950
4602218	Amefa Luer Solo	AMEFA 5 ML 2-TLG	5-0950
4602226	Amefa Luer Solo	AMEFA 10 ML 2-TLG	10-0950
4602234	Amefa Luer Solo	AMEFA 20 ML 2-TLG	20-0950
4606058	PP 5,3 ml Luer Solo	EINMALSPRITZE 2TLG. 5,3ML PFIZER	5-2460
4647068	Injekt® Luer Duo	INJEKT 2 ML 5ER BLOCK 23GX1 1/4"	2-0010/ 0,60-X15
9161450	AS Plus Luer Solo 1 ml	1 ML 2-TLG. SPRITZE GALDERMA	1-3260

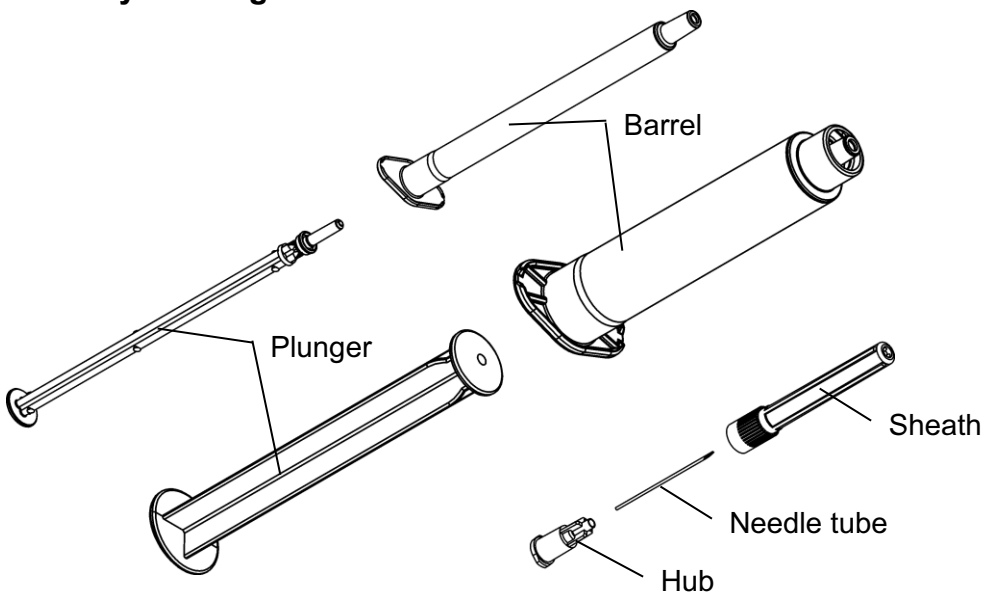
2 Intended use

Single-use syringes, 2-piece

3 Product description

A syringe is a device that predominantly consists of a plunger which fits into a tube (“barrel”). The plunger can be pulled and pushed along inside the tube (“barrel”), allowing the syringe to withdraw or expel a fluid or gas. The open end of the syringe can be fitted with a hypodermic needle, a nozzle, or tubing to help direct the flow into and out of the barrel.
The mechanism of a syringe can be activated by applying a manually physical pressure on the plunger.

3.1 Exploded assembly drawing



3.2 Material

Individual components	Material	
Syringe Barrel	Polypropylene	PP
Plunger	Polyethylene	PE
Packaging Paper	Medical Grade Paper	Paper
Film	Polypropylene/Polyamide/Polyethylene	PP/PA/PE

Effective

3.3 Basic Product Characteristics

The single use syringes contain for their function and purpose the following elements:

- Sizes available: 1 mL - 20 mL
- Optional with detached single-use hypodermic needle
- Highly transparent barrel
- Permanent marking
- Good readability
- 1 mL with displacement spike: reduces the residual volume and minimizes unnecessary loss of medicament
- Safe plunger backstop
- Silicone oil free
- Latex-free
- According to ISO 7886-1
- Available with Luer Slip (1 mL - 20 mL) or Luer Lock (2 mL - 20 mL)

3.4 Packaging

Primary Packaging:	Individual single peel pack designated as a microbiological barrier to assure the sterility of the product.
Secondary Packaging:	Box containing a certain number of primary packaging. 100 pcs. per box.
Transport Packaging:	Case for dispatching and additional protection against mechanical damages during transportation.

4 Product classification[1]

Classification according to the Council Directive 93/42/EEC concerning medical devices Annex IX:

Non-invasive medical devices - Class I sterile, rule 2, additional control function
(class Ism = class I with measurement function):

Single-use syringes, 2-piece (without needle)

- Standard syringes:
  Product groups: *Luer Solo*[2] (e.g. Injekt® Luer Solo)
  Luer Lock Solo (e.g. Injekt® Luer Lock Solo)
- Fine dosage syringes (for precise dosage of smallest volumes):
  Product groups: *F Luer Solo* (e.g. Injekt®-F Luer Solo)
- Fine dosage syringes (for Heparin 10 000 I.U./mL or 25 000 I.U./mL)
  Product group: *H Luer Solo* (e.g. Injekt®-H Luer Solo)

Non-invasive medical devices - Class IIa, rule 6, additional control function:

Single-use syringes, 2-piece (with detached needle)

- Standard syringes:
  Product groups: *Luer Duo*[3] (e.g. Injekt® Luer Duo)
- Fine dosage syringes (for precise dosage of smallest volumes)
  Product group: *F Luer Duo* (e.g. Injekt®-F Luer Duo)
- Fine dosage syringes (for Heparin 10 000 I.U./mL or 25 000 I.U./mL):
  Product group: *H Luer Duo* (e.g. Injekt®-H Luer Duo)

[1] The Classification has to occur from the party responsible for manufacture
[2] Solo: without needle
[3] Duo: with detached needle

Effective

5 General requirements

The products fulfill the requirements of the standards in force at the time of manufacture.

Biological requirements

EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN ISO 10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5	Biological evaluation of medical devices - Part 5:Tests for in vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 11737-1	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
DIN 58953-6	Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized
Ph. Eur.,	European Pharmacopoeia
chapter 2.6.8	Pyrogens
chapter 2.6.14	Bacterial Endotoxins

Chemical requirements

ISO 7886-1	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
EN ISO 10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of materials
Ph. Eur.,	European Pharmacopoeia
chapter 3.2.8	Sterile Single-Use Plastic Syringes

Physical-technical requirements

ISO 7864	Sterile hypodermic needles for single use
ISO 7886-1	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
EN 1707	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings
EN 20594-1	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements

Packaging

EN 868-5	Packaging for terminally sterilized medical devices Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
EN ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
DIN 55529	Verpackung – Bestimmung der Siegelnahtfestigkeit von Siegelungen aus flexiblen Packstoffen
ASTM F 88	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F 1929	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM D 4169	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F 2096	Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)

Sterilization

EN 556-1	Sterilization of medical devices - Requirements for medical device to be designated "STERILE - Part 1: Requirements for terminally sterilized medical devices
EN ISO 11135	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices

Delivery

The products are supplied in individual, sterile packs.

Shelf life

The product shelf life is 60 months.

Storage conditions

EN 1041	Medical devices; Information supplied by the manufacturer No specific storage conditions Storage as commonly used for medical products

Transport conditions

EN 1041	Medical devices; Information supplied by the manufacturer No specific storage conditions Storage as commonly used for medical products

6 Sterilization method

The product is EO sterilized.
The EO residuals are according to EN ISO 10993-7.

7 Properties

Properties	Standard
Biology	
- Haemolysis	EN ISO 10993-4
- Cytotoxicity	EN ISO 10993-5
- Sensitization	ISO 10993-10
- Intracutaneous Reactivity	ISO 10993-10
- Systemic toxicity (acute)	EN ISO 10993-11
- Microbial contamination	EN ISO 11737-1
- Bacterial endotoxins (LAL)	Ph. Eur., chapter 2.6.14
- Pyrogens	Ph. Eur., chapter 2.6.8
- Microbial barrier properties (in case of wetness)	EN ISO 11607-1 / DIN 58953-6
- Sterile	EN 556-1 / EN ISO 11135
- Sterilization residuals	EN ISO 10993-7
Chemistry	
- Extractable metals	ISO 7886-1
- Chemical characterization of materials	EN ISO 10993-18
- Appearance of solution	Ph. Eur., chapter 3.2.8
- Acidity or alkalinity	Ph. Eur., chapter 3.2.8
- Absorbance	Ph. Eur., chapter 3.2.8
- Reducing substances	Ph. Eur., chapter 3.2.8
- Transparency/Opalescence	Ph. Eur., chapter 3.2.8
Technical	
Tightness	
- Air tightness of syringe at vacuum	ISO 7886-1, Annex B
- Fluid tightness of syringe with deflected plunger under compression	ISO 7886-1, Annex D
- Water tightness of syringe and needle during injection	-/-
- Air tightness of conical fitting assembly at vacuum	EN 20594-1 / EN 1707
- Fluid tightness of conical fitting assembly under compression	EN 20594-1 / EN 1707
Tensile / Pressure Strength	
- Breakaway force of syringe with water	ISO 7886-1, Annex E
- Sliding force of syringe with water	ISO 7886-1, Annex E
- Breakaway force of syringe with air	-/-
- Sliding force of syringe with air	-/-
- Secondary starting force of syringe with air	-/-
- Separation force of plunger out of barrel	-/-
- Separation force of fitting assembly	EN 20594-1 / EN 1707
- Flexural strength of barrel finger grips	-/-

Properties	Standard
Visual	
- Contamination of device	ISO 7886-1
- Damages of device	-/-
- Completeness of device	-/-
- Shaping of device	-/-
- Coloration of single parts and graduation	-/-
- Graduated scale of syringe	ISO 7886-1
- Wipe resistance of graduation	-/-
- Material projections of device	-/-
- Inclusions / flakes / bubbles / flow marks of single parts	-/-
- Transparency of syringe barrel	-/-
Function	
- Maximum dead space	ISO 7886-1, Annex C
- Tolerance on graduated capacity	ISO 7886-1
- Rolling behavior at 10°	ISO 7886-1
- Fit of plunger in barrel	ISO 7886-1
- Patency of syringe lumen	-/-
- Unscrewing torque of fitting assembly	EN 1707
- Ease of assembly of fitting assembly	EN 1707
- Resistance to overriding of fitting assembly	EN 1707
- Stress cracking of fitting assembly	EN 20594-1 / EN 1707
Dimensional accuracy	
- Luer conical fitting (male/female)	EN 20594-1 / EN 1707
- Position of scale - zero graduation line	ISO 7886-1
- Maximal useable capacity	-/-
- Minimum length of the plunger from the surface of the finger grips nearer to the push-button	ISO 7886-1
- Diameter of nozzle lumen	ISO 7886-1
Additional Tests	
Needles Certificate of Conformity	ISO 7864

Properties	Standard
Packaging	
Tightness	
- Air tightness of primary packaging (bubble test)	ASTM F 2096
- Fluid tightness seal seam of primary packaging (blue dye test)	ASTM F1929
Tensile / Pressure Strength	
- Strength of sealing seam, primary packaging	DIN 55529 / ASTM F 88
Visual	
- Labeling of all packages	ISO 7886-1
- Printing quality of all packages	ISO 7886-1
- Cleanliness of primary packaging	ISO 7886-1
- Contamination of all packages except primary packaging	ISO 7886-1
- Damages of all packages	-/-
- Closure of all packages	-/-
- Completeness of all packages	-/-
Function	
- Peelability of sealing seam, primary packaging	EN 868-5, Annex E
- Separation of primary packaging	-/-
Dimensional accuracy	
- Width of sealing seam, primary packaging	EN 868-5, Annex E

8 Appendices

none

– End of document –

9 Document administration

9.1 Amendment information

Version	Description of the changes
12.0	Article deletion (4645049, 4645122-03, 4645050); 4647068 was moved from local to OEM; Articles FC0020010, FC0050010 and FC0100010 were moved into specification RMF-092-500-PS-01; 4 Product Classification: Information reduced to medical device acc. to EU regulation. Other information listed in Document No. RMF-094-002-IU (Document ID BB-GMS-MD-002113); ISO 868-5 was corrected into EN 868-5; 'Incompatibility with injection fluids' was deleted acc. to HC-CHC-ALMO-463; Feature 'Chemical characterization of materials' was moved from Biology into Chemistry; 'Cleanliness of device' was renamed into 'Contamination of device'; 'Cleanliness of all packages' was divided into 'Cleanliness of primary packaging' and 'Contamination of all packages except primary packaging'; Following features were deleted acc. to HC-CHC-ALMO-569 – harmonization with Product Risk Analysis: 'Flexural strength of Luer cone', 'Dimension according to drawing', 'Minimal film thickness of primary packaging'
11.0	Article deletion (FC0010010)
10.0	5 General requirements: ISO 8536-4 deleted; EN ISO 11135-1 replaced by EN ISO 11135 (HC-CHC-ALMO-394)
9.0	Changes of Section 7 according to HC-CHC-ALMO-408: 'Particulate contamination' were deleted; The designation 'Barrel length' was changed in 'Maximal useable capacity' and the reference to ISO 7886-1 was deleted; Adaption of the designation 'Needles acc. to 7864 – Certificate of Conformity'; Change Annex G into Annex E for 'Breakaway and Sliding force of syringe with water'; Article deletion (4645070)
8.0	Add Section 3 Product Description and 3.4 Packaging; Update Section 4 acc. to RMF-094-002-IU, Version 2.0; ISO 868-5 was added to Section 5 as well as Microbial barrier properties, sorting properties acc. to current requirements
7.0	Article deletion (4645030)
6.0	Articles were deleted (4647220-03, 4647222-03)
5.0	Article was deleted (FC0200013) Referenced standard EN 868-5 was deleted (HC-CHC-ALMO-149)
4.0	Articles were added (4647220-03, 4647222-03) Articles were deleted (FC0020012, FC0050012, FC0100012, FC0200010, 871881, 871898, 871904, 871911, 871928, 871935, 871942, 4608323, 4608340, 4608366, 4608374, 4648323, 4648340, 4648350, 4648358, 4648366, 4648374)
3.0	Articles were deleted (4645002, 4645005, 4647220-03, 4647222-03)
2.0	Needle drawings were added in the Scope, the Product Classification was updated
1.0	New specification

Effective

Title: Two-piece Syringe - Product Specification 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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