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1 Scope

The Product specification applies to the following products:

Local

Article No.	Product Name	Designation	Drawing
NJ-4606027	NORM-JECT® Luer Solo	2 ML NORM-JECT BBRAUN	2-1470
NJ-4606051	NORM-JECT® Luer Solo	5 ML NORM-JECT BBRAUN	5-1470
NJ-4606067	NORM-JECT® Luer Solo	5 ML NORM-JECT ZENTRISCH BBRAUN	5-3920
NJ-4606108	NORM-JECT® Luer Solo	10 ML NORM-JECT BBRAUN	10-1470
NJ-4606110	NORM-JECT® Luer Solo	10 ML NORM-JECT ZENTRISCH BBRAUN	10-3920
NJ-4606205	NORM-JECT® Luer Solo	20 ML NORM-JECT BBRAUN	20-1470
NJ-4606701	NORM-JECT® Luer Lock Solo	2 ML NORM-JECT LL BBRAUN	2-3420
NJ-4606710	NORM-JECT® Luer Lock Solo	5 ML NORM-JECT LL BBRAUN	5-3420
NJ-4606728	NORM-JECT® Luer Lock Solo	10 ML NORM-JECT LL BBRAUN	10-3420
NJ-4606736	NORM-JECT® Luer Lock Solo	20 ML NORM-JECT LL BBRAUN	20-3420
NJ-9166017	NORM-JECT®-F Luer Solo	1 ML NORM-JECT-F BBRAUN	1-Z0160

OEM

Article No.	Product Name	Designation	Drawing
NJ-4606027-02	NORM-JECT® Luer Solo	2 ML NORM-JECT BBRAUN US	2-1470
NJ-4606051-02	NORM-JECT® Luer Solo	5 ML NORM-JECT BBRAUN US	5-1470
NJ-4606067-02	NORM-JECT® Luer Solo	5 ML NORM-JECT ZENTRISCH BBRAUN US	5-3920
NJ-4606108-02	NORM-JECT® Luer Solo	10 ML NORM-JECT BBRAUN US	10-1470
NJ-4606110-02	NORM-JECT® Luer Solo	10 ML NORM-JECT ZENTRISCH BBRAUN US	10-3920
NJ-4606205-02	NORM-JECT® Luer Solo	20 ML NORM-JECT BBRAUN US	20-1470
NJ-4606701-02	NORM-JECT® Luer Lock Solo	2 ML NORM-JECT LL BBRAUN US	2-3420
NJ-4606710-02	NORM-JECT® Luer Lock Solo	5 ML NORM-JECT LL BBRAUN US	5-3420
NJ-4606728-02	NORM-JECT® Luer Lock Solo	10 ML NORM-JECT LL BBRAUN US	10-3420
NJ-4606736-02	NORM-JECT® Luer Lock Solo	20 ML NORM-JECT LL BBRAUN US	20-3420
NJ-9166017-02	NORM-JECT®-F Luer Solo	1 ML NORM-JECT-F BBRAUN US	1-Z0160

Effective

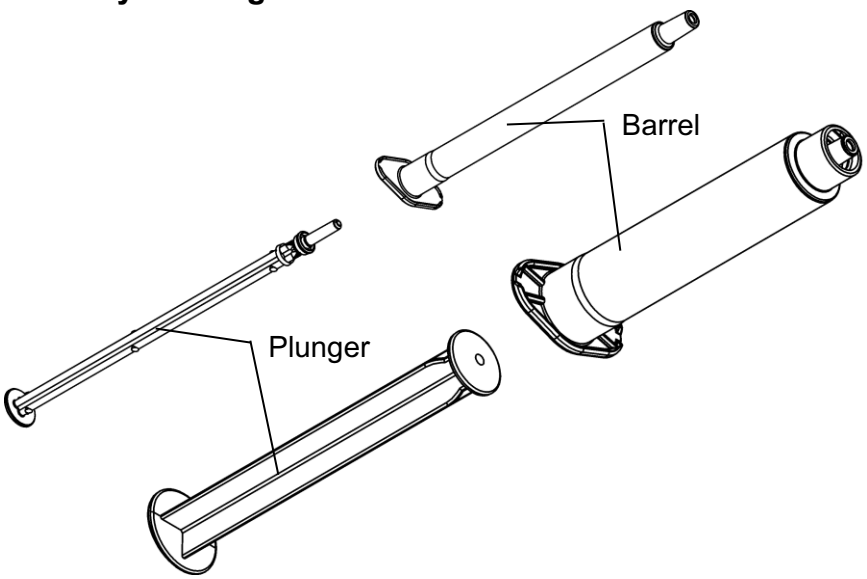
2 Intended use

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
- 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. NORM-JECT® Luer Solo)
  Luer Lock Solo (e.g. NORM-JECT® Luer Lock Solo)
- Fine dosage syringes (for precise dosage of smallest volumes):
  Product groups: *F Luer Solo* (e.g. NORM-JECT®-F Luer Solo)

[1] The Classification has to occur from the party responsible for manufacture
[2] Solo: without 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 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

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
3.0	OEM devices (NORM-JECT® US) were added
2.0	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'
1.0	New specification

Title: Two-piece Syringe (NORM-JECTÂ®) - Product Specification Initiator: Martina ? Schreiber

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