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Reference: SOP HO-DDDD-M-5-2-04-536 Preparation of product- and test specifications
Template based on HO-DDDD-M-5-2-04-536-01, Version 7.0, Document ID BPP HC-DIV 850

1 Scope

The Product specification applies to the following products:

RMF:	**094-002**		**Shelf-Life: 60 months**
Basic UDI-DI:	**N/A**		
Article no.	Product name	Designation	Drawing
Market Scope: Global			
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
9166017V	Injekt®-F Luer Solo	INJEKT 1 ML FINE DOSAGE	1-1320
Market Scope: Local			
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 CENTRIC 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 CENTRIC BBRAUN	10-3920
NJ-4606205	NORM-JECT® Luer Solo	20 ML NORM-JECT BBRAUN	20-1470
NJ-9166017	NORM-JECT®-F Luer Solo	1 ML NORM-JECT-F BBRAUN	1-Z0160
Market Scope: B2B			
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	SINGLE-USE SYRINGE 2-PIECE 5,3ML PFIZER	5-2460
9161450	AS Plus Luer Solo 1 ml	1 ML 2-PART SYRINGE GALDERMA	1-3260
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 CENTRIC BBRAUN AIR-TITE	5-3920
NJ-4606108-02	NORM-JECT® Luer Solo	10 ML NORM-JECT BBRAUN US	10-1470

Basic UDI-DI:	**N/A**		
Article no.	Product name	Designation	Drawing
NJ-4606110-02	NORM-JECT® Luer Solo	10 ML NORM-JECT CENTRIC BBRAUN AIR-TITE	10-3920
NJ-4606205-02	NORM-JECT® Luer Solo	20 ML NORM-JECT BBRAUN US	20-1470
NJ-9166017-02	NORM-JECT®-F Luer Solo	1 ML NORM-JECT-F BBRAUN US	1-Z0160

Basic UDI-DI:	**N/A**		
Article no.	Product name	Designation	Drawing
Market Scope: Global			
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
Market Scope: Local			
9166203V	Injekt®-H Luer Solo	INJEKT 1 ML HEP INNOHEP 20.000 ANTI-XA	1-1460

Basic UDI-DI:	**N/A**		
Article no.	Product name	Designation	Drawing
Market Scope: Global			
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
Market Scope: Local			
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-4606736	NORM-JECT® Luer Lock Solo	20 ML NORM-JECT LL BBRAUN	20-3420
Market Scope: B2B			
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	NORM-JECT® Luer Lock Solo	10 ML NORM-JECT LL BBRAUN	10-3420
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-4606755BMS	NORM-JECT® Luer Lock Solo	10 ML NORM-JECT® LL BMS	10-4210

Basic UDI-DI:	**N/A**		
Article no.	Product name	Designation	Drawing
Market Scope: Global			
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
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
9166033V	Injekt®-F Luer Duo	INJEKT 1 ML FINE DOSAGE DUO 25GX5/8"	1-1320/ 0,50-X15
Market Scope: Local			
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
4645022UA	Injekt® Luer Duo	INJEKT 2 ML DUO 23GX1 1/4" UA	2-1390/ 0,60-X15
4645057UA	Injekt® Luer Duo	INJEKT 5 ML DUO 22GX1 1/4" UA	5-1390/ 0,70-X15
4645103UA	Injekt® Luer Duo	INJEKT 10 ML DUO 21GX1 1/2" UA	10-1390/ 0,80-X15
4645200UA	Injekt® Luer Duo	INJEKT 20 ML DUO 21GX1 1/2" UA	20-1390/ 0,80-X15

Basic UDI-DI:	**N/A**		
Article no.	Product name	Designation	Drawing
Market Scope: Local			
9166297	Injekt®-H Luer Duo	INJEKT 1 ML HEPA 25.000IE DUO 26GX1/2"	1-1330/ 0,45-X15

Basic UDI-DI:	**N/A**		
Article no.	Product name	Designation	Drawing
Market Scope: Global			
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
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

2 Intended Use / Purpose and Classification

BASIC UDI-DI: N/A

Description on the label:
Single-use syringes, 2-piece
Single-use fine dosage syringes, 2-piece

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

Product name	Conformity assessment procedure	Classification	Rule	Paragraph
Single-use syringes, 2-piece (without needle) *Standard syringes:* Product group: *Luer Solo*[1] e.g. Injekt® Luer Solo Product group: *Luer Lock Solo*[1] e.g. Injekt® Luer Lock Solo *Fine dosage syringes* (for precise dosages of smallest volumes): Product group: *F Luer Solo*[1] 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*[1] e.g. Injekt®-H Luer Solo	V	Ism	**2**	N/A
Single-use syringes, 2-piece (with detached needle) *Standard syringes:* Product group: *Luer Duo*[2] e.g. Injekt® Luer Duo *Fine dosage syringes:* (for precise dosages of smallest volumes): Product group: *F Luer Duo*[2] 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*[2] e.g. Injekt®-H Luer Duo	II (excluding section 4)	IIa	**6**	N/A

[1] Solo: without needle
[2] Duo: with detached needle

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Classification according to the GMDN Code (GMDN = Global Medical Device Nomenclature)

Product name	GMDN Code	GMDN Designation
Single-use syringes, 2-piece as defined in the Declaration of Conformity	35904	Syringe, hypodermic, metered delivery

Classification according to the UMDNS Code
(UMDNS = Universal Medical Device Nomenclature System)

Product name	UMDNS Code	UMDNS Designation
Single-use syringes, 2-piece as defined in the Declaration of Conformity	13-940	Syringe, Hypodermic

3 Product description

This chapter gives information on the important product functions within the Intended Use.

3.1 Exploded assembly drawing

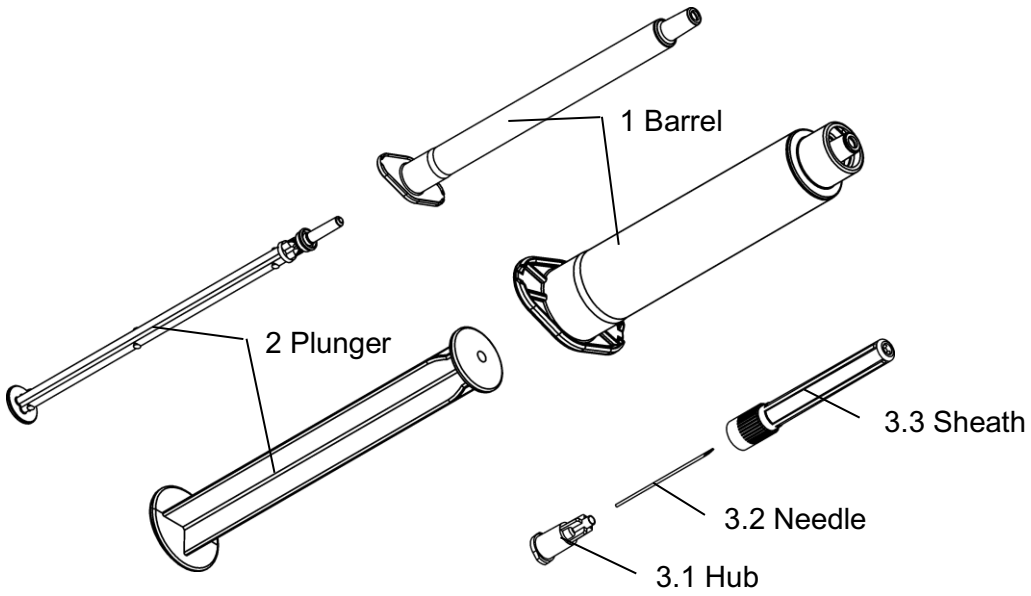

Fig. 1 Exploded assembly drawing

3.2 All components / complete set

The 2-piece syringe is a sterile single-use hypodermic syringe that is made of plastic material. It consists of two pieces: a plunger which is fitted in a barrel. In order to activate the 2-piece syringe, physical pressure has to be applied to the plunger in terms of pulling or pushing. By pulling the plunger, the 2-piece syringe is filled through the cone of the syringe. By applying pressure on the plunger, the content of the 2-piece syringe is pressed through the cone of the syringe. The position of the plunger as well as the graduation on the 2-piece syringe barrel indicate the fluid volume that is in the syringe.

A 2-piece syringe has a conical fitting in form of either Luer Lock or Luer Slip cone. With these Luer connectors, the 2-piece syringe is compatible with other medical devices that have Luer connectors, e.g. needles, extension lines or valves.

3.3 Components and materials

No.	Component	Material/Polymer type	Material Abbreviation
1	Barrel		
1.1	Granulate	Polypropylene	PP
1.2	Graduation	Printing Ink	N/A
2	Plunger		
2.1	Granulate	Polyethylene	PE
2.2	Masterbatch	Colorant	N/A
3	Needle		
3.1	Hub	Polypropylene	PP
3.2	Needle tube	Stainless steel	N/A
3.3	Sheath	Polyethylene or Polypropylene	PE or PP
4.1	Primary Packaging		
4.1.1	Paper	Medical Grade Paper	Paper
4.1.2	Film	Polypropylene/Polyamide/Polyethylene	PP/PA/PE

3.4 Basic product characteristics and features

- 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
- According to ISO 7886-1
- Available with Luer Slip (1 mL - 20 mL) or Luer Lock (2 mL - 20 mL)
- not made with silicone oil
- not manufactured with DEHP
- not manufactured with Latex/Natural Rubber
- not manufactured with PVC
- non-pyrogenic

3.5 Packaging

Packaging consists of primary packaging units arranged in a carton:

Primary Packaging (sterile barrier system, SBS):	Individual single peel pack designated as a microbiological barrier to assure the sterility of the product.
Secondary Packaging (protective packaging, PP):	Box for dispatching and additional protection against mechanical damages during transportation. Box containing a certain number of primary packaging. In general 100 pcs. per box. NJ-4606755BMS – 90 pcs. per box.
Transport Packaging (protective packaging, PP):	Case for dispatching and additional protection against mechanical damages during transportation. Case containing a certain number of secondary packaging.

4 General requirements

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

Chemical requirements

ISO 7886-1	Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
ISO 10993-18 / EN ISO 10993-18	Biological evaluation of medical devices – Part 18: Chemical characterization of materials
Ph. Eur. chapter 3.3.8	European Pharmacopoeia Sterile Single-Use Plastic Syringes

Biological requirements

ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system
ISO 10993-4 / EN ISO 10993-4	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
ISO 10993-5 / 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
ISO 10993-11 / EN ISO 10993-11	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
ISO 11737-1 / EN ISO 11737-1	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
Ph. Eur. chapter 2.6.14	European Pharmacopoeia Bacterial Endotoxins

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
ISO 11607-1 / EN ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2 / EN ISO 11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
ISO 15223-1 / EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
DIN 58953-6	Sterilization – Sterile supply – Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized
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 Packaging by Internal Pressurization (Bubble Test)

Sterilization

EN 556-1	Sterilization of medical devices – Requirements for medical devices to be designated ‘STERILE’ – Part 1: Requirements for terminally sterilized medical devices
ISO 10993-7 / EN ISO 10993-7	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
ISO 11135 / EN ISO 11135	Sterilization of health care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices

Cleanroom

ISO 14644-1	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration
	Cleanroom designation: ISO Class 9; operational; 0.5 µm, 5 µm

Storage conditions

EN 1041	Information supplied by the manufacturer of medical devices
	No special storage conditions
	Storage as commonly used for medical products

Transport conditions

EN 1041	Information supplied by the manufacturer of medical devices
	No special storage conditions
	Storage as commonly used for medical products

5 Sterilization method

The product is EO sterilized.
The EO Residuals are acc. to ISO 10993-7 / EN ISO 10993-7.

– End of document –

6 Document History

Version	Description of the changes
19.0	Transfer into new template version; Article 4645022UA, 4645057UA, 4645103UA and 4645200UA were added to the scope (see also HC-CHC-M-DIV-2395)
18.0	Change of Document Name '2-piece syringe' was 'Two-piece Syringe'; Basic UDI-DIs were deleted (N/A for MDD) - HC-CHC-M-DIV-2024; Change of Document No (RMF-094-002-PS-01 was RMF-092-001-PS-01); DIN 55529 was deleted; Ph. Eur. chapter 3.3.8 was Ph. Eur. chapter 3.2.8; Drawing No for NJ-4606755BMS was changed from 10-3420 into 10-4210 (cf. also HC-CHC-ALMO-898); B2B was OEM
17.0	NJ-4606728 – change Market Scope from local into OEM (acc. to Change Request HC-CHC-ALMO-802); NJ-4606755BMS was added acc. to Change Request HC-CHC-ALMO-805; 3.5 Packaging, additional quantity was added; 4647068 was deleted; Basic UDI-DIs were corrected for 2-piece syringes IS (L/Heparin/LL)
16.0	Transfer into new template incl. deletion of the chapter 'properties'; add BASIC UDI-DI; Include article No from RMF-092-300-PS-01 (NORM-JECT®) / Document ID: SPEC-RD-IVS-001194 acc. to Change Control HC-CHC-M-DIV-1911; Change of Document No (RMF-092-001-PS-01 was RMF-094-002-PS-01)
15.0	Transfer into new template; Chapter 3.5 was harmonized with Intended Use (RMF-094-002-IU - Document ID: BB-GMS-MD-002113); The description of the Properties was harmonized with standard resp. test method; 'Microbial barrier properties (in case of wetness)' was moved from biology into Packaging as 'SBS – Germ proofness under humidity; 'Material-mediated Pyrogenicity' and 'Subacute Systemic Toxicity' were added; 'Pyrogens', 'Water tightness of syringe an needle during injection', 'Breakaway force of syringe with air', 'Sliding force of syringe with air', 'Secondary starting force of syringe with air', 'Flexural strength of barrel finger grips' and 'Patency of syringe lumen' was deleted; 'Readability of Data Matrix Code', 'Readability of Barcode' and 'Position of graduation - zero line' for 1 mL as visual inspection were added
14.0	Chapter 3.2: Add information regarding hypodermic needle
13.0	Article deletion (4647240-03, 4645023-03, 4645024-03, 4645021-03, 4645200V-03)
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';

Effective

Version	Description of the changes
	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' was 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

Title: 2-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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