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KD Medical GmbH Hospital Products · Charlottenstrasse 65 · 10117 Berlin · Germany

Summary Essential Technical Data - KD-JECT III - Sterile syringes for single use

Manufacturer: KD Medical GmbH Hospital Products
Charlottenstraße 65
10117 Berlin
GERMANY

Product: Syringes Insulin
(Sterile Insulin syringes for single use (three parts))

Brand: KD-JECT III

UMDNS code: 13-941

Risk Class: IIa according to rule 6 of Annex IX of Council Directive 93/42/EEC,
amended by Council Directive 2007/47/EC

Conformity assessment procedure: according to Annex II, section 3 of Council Directive 93/42/EEC,
amended by Council Directive 2007/47/EC

Notified Body: TÜEV Süd Product Service GmbH
Ridlerstraße 65
80339 Munich, Germany
Identification no 0123

Brief description of the product

KD-JECT III sterile Insulin syringes for single use consist of the following parts - barrel, plunger, gasket (rubber seal) and protective cap. Variants with intergrated or mounted needle include a needle tube with protective cap.

These syringes are intended for the injection of precise quantities of insulin for treatment of diabetes mellitus. They are easy to handle so that - after adequate training - they can be used by the diabetic patients themselves.

They are non-toxic, pyrogen-free and have been sterilized by ethylene oxide.

Latex-containing and latex-free variants are available (specifications see below).

Usage of disposable syringes can avoid cross-infections between patients.

Variants: drawings and material specification:

Material valid for all variants:

Syringes	
Barrel:	Ethylene Polypropylene Copolymer (PP)
Plunger:	Ethylene Polypropylene Copolymer (PP)
Protective cap:	Ethylene Polypropylene Copolymer (PP)
Rubber seal (gasket)	latex variants: natural rubber (polyisoprene)
	latex-free variants: synthetic rubber (polyisoprene)
Lubricant	Silicone oil
Needle (if applicable):	
needle hub:	Ethylene Polypropylene Copolymer (PP)
needle tube:	Stainless steel
Protective cap:	Ethylene Polypropylene Copolymer (PP)

Bank	Deutsche Bank AG, Berlin	Commerzbank AG, Berlin	Registered Office: Berlin
Bank Code	100 700 00	100 800 00	Managing Director: Jörg Bartz
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Drawing of a representative product:



1, 6: Protective cap, 2: needle tube, 3: rubber seal (gasket), 4: barrel, 5: plunger

Sterilization: by Ethylene oxide (EO)

Latex: There are two variants of KD-JECT III: latex and latex-free details s. under "Variants"

Shelf life: 5 years from the date of manufacture
Note: dates of manufacture and expiry are printed on each individual package

Storage: Do not store at extreme temperature and humidity.

Precautions for use: The patient has to be trained before usage of KD-JECT III Insulin syringes.
 Do not use if the pouch is damaged or opened or if the protective cap has fallen off.
 For single use only. To be used immediately after opening.
 Discard after single use to avoid risk of infection.
 The device cannot be used in case the needlepoint is hooked or shows other abnormalities.
 To be used within the validity period

Variants:

A. LATEX containing variants

KD-JECT III, Syringes, Latex, Luer slip, 1 ml (Insulin), mounted needle				
Article no	Size ml	Size of needle	Specification	Quantity export carton
801345	1 ml, U 100	27 G x 1/2" (0.4 x 12 mm)	Insulin	3000
831373	1 ml, U 100	29 G x 1/2" (0.33 x 12 mm)	Insulin	3000
831373	1 ml, U 100	29 G x 1/2" (0.33 x 12 mm)	Insulin	2400
831700	1 ml, U 100	26 G x 1/2" (0.45 x 12 mm)	Insulin	3000
831724	1 ml, U 100	30 G x 1/2" (0.3 x 13 mm)	Insulin	2400
811344	1 ml, U 40	26 G x 1/2" (0.45 x 12 mm)	Insulin	3000
831380	1 ml, U 40	27 G x 1/2" (0.4 x 12 mm)	Insulin	3000
831397	1 ml, U 40	29 G x 1/2" (0.33 x 12 mm)	Insulin	3000

KD-JECT III, Syringes, Latex, UNIBODY, with integrated needle, Insulin				
Article no	Size ml	Size of needle	Specification	Quantity export carton
870181	1, U 40	29 G x 1/2" (0.33 x 12 mm)	Insulin, 10 er plastic bag	2400
870198	1, U 40	30 G x 1/2" (0.3 x 12 mm)	Insulin, 10er plastic bag	2400
870129	1, U 40	29 G x 1/2" (0.33 x 12 mm)	Insulin, blister	2400
870143	1, U 40	30 G x 1/2" (0.3 x 12 mm)	Insulin, blister	2400
870167	1, U 100	29 G x 1/2" (0.33 x 12 mm)	Insulin, 10er plastic bag	1000
870334	1, U 100	30 G x 5/16" (0.3 x 8 mm)	Insulin, 10er plastic bag	500
870082	1, U 100	29 G x 1/2" (0.33 x 12 mm)	Insulin, blister	2400
870747	1, U 100	30 G x 1/2" (0.3 x 12 mm)	Insulin, blister	2400

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B. LATEX-FREE variants

KD-JECT III, Syringes, Latex-free, Luer slip, mounted needle				
Article no	Size ml	Size of needle	Specification	Quantity export carton
831755	1, U 100	29 G x 1/2" (0.33 x 12 mm)	Insulin	3000
870600	1, U 100	27 G x 1/2" (0.4 x 12 mm)	Insulin	3000
831762	1, U 40	29 G x 1/2" (0.33 x 12 mm)	Insulin	3000
831779	1, U 40	27 G x 1/2" (0.4 x 12 mm)	Insulin	3000

KD-JECT III, Syringes, Latex-free, Luer slip, without needle, Insulin				
Article no	Size ml	Size of needle	Specification	Quantity export carton
870624	1, U 100		Insulin	

KD-JECT III, Syringes, Latex-free, Luer lock, without needle, Insulin				
Article no	Size ml	Size of needle	Specification	Quantity export carton
870792	1, U 100		Insulin	

KD-JECT III, Syringes, Latex-free, Luer, UNIBODY: with intergrated needle, Insulin				
Article no	Size ml	Size of needle	Specification	Quantity export carton
870174	1, U 100	30 G x 1/2" (0.3 x 12 mm)	10er plastic bag	500
870228	1, U 100	30 G x 1/2" (0.3 x 12 mm)	10er plastic bag	2400
870303	1, U 100	30 G x 5/16" (0.3 x 8 mm)	10er plastic bag	500
870105	1, U 100	30 G x 1/2" (0.3 x 12.7 mm)	blister	2400
870204	1, U 100	30 G x 1/2" (0.3 x 12 mm)	blister	1000
870501	0.3, U 100	30 G x 5/16" (0.3 x 8 mm)	blister	3600
870518	0.5, U 100	29 G x 1/2" (0.33 x 12.7 mm)	blister	3600
870525	0.5, U 100	30 G x 5/16" (0.3 x 8 mm)	blister	3600
870532	1, U 100	29 G x 1/2" (0.33 x 12.7 mm)	blister	2400
870549	1, U 100	30 G x 5/16" (0.3 x 8 mm)	blister	2400

Issue:
Revision:

06.12.2010
1

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