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

Summary Essential Technical Data - KD-JECT O, KD-JECT E - Oral / Enteral syringes

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

Product: Oral / Enteral syringes

Brand: KD-JECT O (oral syringes)
KD-JECT E (enteral syringes)

UMDNS code: 13-929

Risk Class: Ims according to Annex IX, rule 5 of Council Directive 93/42/EEC,
as amended by Council Directive 2007/47/EC

**Conformity assessment
procedure:** according to Annex V of Council Directive 93/42/EEC,
as amended by Council Directive 2007/47/EC

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich, Germany
Identification no 0123

Brief description of the product

a) KD-JECT O oral syringes

KD-JECT O oral syringes are disposable items intended for transient use (definition as per Annex IX, MDD 93/42/EEC).

Intended use:

KD-JECT O oral syringes are three-part syringes intended for the oral administration of liquid diets or drugs. They are equipped with a connector incompatible to Luer connectors, thereby preventing accidental parenteral administration. The scale allows exact measuring of the volumes to be administered (accuracy of the scale in accordance with ISO 7886-1).

KD-JECT O oral syringes are provided in sterile condition and are intended for single use on a single patient only.

Indications:

- Oral administration of liquid diets or drugs

Contraindications:

- The product must not be used for parenteral applications
- The product must not be used in unconscious patients and patients unable to swallow
- The product must not be used in patients with known hypersensitivity to any of the materials used

b) KD-JECT E enteral syringes

KD-JECT E enteral syringes are disposable items intended for transient use (definition as per Annex IX, MDD 93/42/EEC).

Intended use:

KD-JECT E enteral syringes are three-part syringes equipped with a female ENFit connector. They are intended for the enteral administration of liquid diets or drugs and for enteral aspiration or irrigation procedures. The scale allows exact measuring of the volumes to be administered or aspirated (accuracy of the scale in accordance with ISO 7886-1).

KD-JECT E enteral syringes are provided in sterile condition and are intended for single use on a single patient only.

Indications:

- Enteral administration of liquid diets or drugs via feeding tubes/extensions tubes equipped with ENFit compatible male connectors
- Enteral aspiration and irrigation procedures via tubes equipped with ENFit compatible male connectors

Contraindications:

- The product must not be used for parenteral applications
- The product must not be used in patients with known hypersensitivity to any of the materials used

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Compatibility with other (medical) devices:

KD-JECT E enteral syringes are equipped with a female ENFit connector conforming to with ISO 80369-3 that provides compatibility with enteral feeding systems and accessories that are equipped with a male enteral small-bore connector conforming to ISO 80369-3. ENFit connectors conforming to ISO 80369-3 are designed to help preventing accidental parenteral administration.

KD-JECT O oral syringes are equipped with a connector incompatible to Luer connectors, thereby preventing accidental parenteral administration.

Performance:

Accuracy of the scale as stipulated in ISO 7886-1:

Nominal capacity of syringe, V ml	Tolerance on any graduated capacity	
	Less than half nominal capacity	Equal to or greater than half nominal capacity
$V < 2$	$\pm(1.5\% \text{ of } V + 2\% \text{ of expelled volume})$	$\pm 5\% \text{ of expelled volume}$
$2 \leq V < 5$	$\pm(1.5\% \text{ of } V + 2\% \text{ of expelled volume})$	$\pm 5\% \text{ of expelled volume}$
$5 \leq V < 10$	$\pm(1.5\% \text{ of } V + 1\% \text{ of expelled volume})$	$\pm 4\% \text{ of expelled volume}$
$10 \leq V < 20$	$\pm(1.5\% \text{ of } V + 1\% \text{ of expelled volume})$	$\pm 4\% \text{ of expelled volume}$
$20 \leq V < 30$	$\pm(1.5\% \text{ of } V + 1\% \text{ of expelled volume})$	$\pm 4\% \text{ of expelled volume}$
$30 \leq V < 50$	$\pm(1.5\% \text{ of } V + 1\% \text{ of expelled volume})$	$\pm 4\% \text{ of expelled volume}$
$50 \leq V$	$\pm(1.5\% \text{ of } V + 1\% \text{ of expelled volume})$	$\pm 4\% \text{ of expelled volume}$

Further requirements as stipulated in ISO 7886-1, ISO 80369-1 (KD-JECT E), ISO 80369-3 (KD-JECT E) and ISO 20695 (KD-JECT E).

Provisions and standards applied:

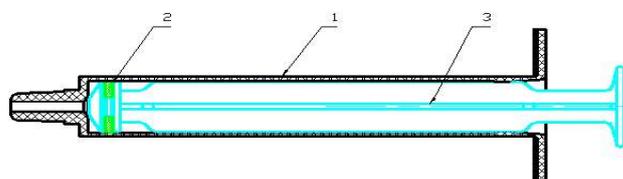
indicated in document "List of provisions and standards applied", identifier PO373lms-3.

Drawing and Material specification:

Materials of animal origin:

The product and packaging/packing do not contain any constituents of animal origin.

a) KD-JECT O oral syringes



Item number as per above drawing	Component	Material	Further specification
1	Barrel	Polypropylene (PP)	PP 5250T
2	Gasket	Silicone rubber (latex-free)	N/A
3	Plunger	Polypropylene (PP)	PP 5250T
-	Lubricant	Silicone oil	DC 360

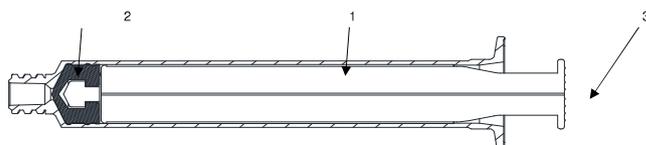
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b) KD-JECT E enteral syringes



Item number as per above drawing	Component	Material	Further specification
1	Barrel	Polypropylene (PP)	PP 5250T
2	Rubber seal	Isoprene rubber (latex-free)	N/A
3	Plunger	Polypropylene (PP)	PP 5250T
-	Lubricant	Silicone oil	DC 360

DEHP: KD-JECT O oral syringes and KD-JECT E enteral syringes are DEHP-free.

Latex: KD-JECT O oral syringes and KD-JECT E enteral syringes are latex-free.

Pyrogenicity: KD-JECT O oral syringes and KD-JECT E enteral syringes are non-pyrogenic.

Sterilization: by Ethylene oxide (EO)

Shelf life: 5 years from the date of manufacture

Storage: Store in a clean and dry place. Store away from sunlight. Do not store at extreme temperatures.

Disposal: Discard the product after single use in accordance with pertinent national and institutional guidelines.

- Cautions:**
- Read instructions before use.
 - Use of this product is restricted to qualified healthcare professionals.
 - Visually inspect and check the product and package integrity prior to use and also the expiry date. Improper transport and handling may cause structural and/or functional damage to device or packaging.
 - Do not use if the syringe is damaged/deformed/blocked.
 - Do not use if the individual package is damaged.
 - Do not use after the expiry date.
 - Use the product immediately after opening the individual package.
 - For single use on a single patient only. Re-use of single use devices creates a potential risk for patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.
 - Discard after single use. Do not recycle, reprocess or re-sterilize.

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Packing data:

Packing unit	Material	pieces per packing unit
individual package (blister)	PP/PE-film + adhesive coated paper (63 g/m ²)	1
Inner box	E-corrugate paper	1 - 20 ml: 100 60 ml: 30 100 ml: 20
Export carton	BA-double corrugate paper	1 ml: 3600 3 ml: 3200 5 ml: 2400 10 ml: 1500 20 ml: 900 60 ml: 300 100 ml: 120

Variants:

a) KD-JECT O, oral syringes

Article number	Specification
876244	Oral Syringe, sterile, single-use, 1ml
876251	Oral Syringe, sterile, single-use, 3ml
876268	Oral Syringe, sterile, single-use, 5ml
876275	Oral Syringe, sterile, single-use, 10ml
876282	Oral Syringe, sterile, single-use, 20ml

b) KD-JECT E, enteral syringes with ENFIT connector (ISO 80369-3)

Article number	Specification
875674	Enteral Syringe (ENFIT), sterile, purple, single-use, centric, 1ml
875681	Enteral Syringe (ENFIT), sterile, purple, single-use, centric, 3ml
875698	Enteral Syringe (ENFIT), sterile, purple, single-use, centric, 5ml
875704	Enteral Syringe (ENFIT), sterile, purple, single-use, centric, 10ml
875711	Enteral Syringe (ENFIT), sterile, purple, single-use, centric, 20ml
875728	Enteral Syringe (ENFIT), sterile, purple, single-use, eccentric, 60ml
876381	Enteral Syringe (ENFIT), sterile, purple, single-use, centric, 100ml

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