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

Summary Essential Technical Data - KD-FLY sterile scalp vein sets for single-use

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

Product: Scalp Vein Sets
(Sterile scalp vein sets for single-use)

Brand: KD-FLY

UMDNS code: 17-825

Risk Class: IIa according to Annex IX, rule 7 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: TUEV Süd Product Service GmbH
Ridlerstraße 65
80339 Munich, Germany
Identification no 0123

Brief description of the product

KD-FLY scalp vein sets are venipuncture devices intended for the collection of blood, for short-term infusions / transfusions or for the intravenous administration of drugs.

They are sterile, non-pyrogenic and non-toxic. Usage of these disposable items can avoid cross-infections between patients.

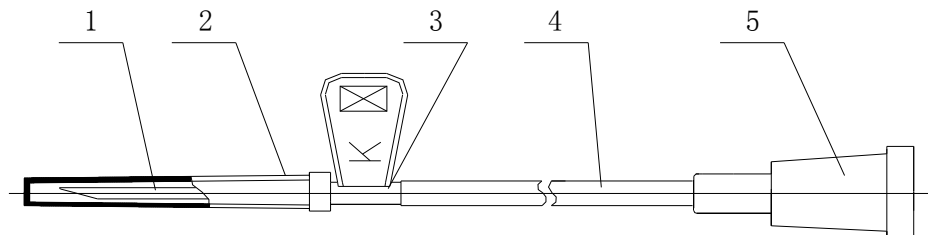
Bank	Deutsche Bank AG, Berlin	Commerzbank AG, Berlin	Registered Office: Berlin
Bank Code	100 700 00	100 800 00	Managing Director: Jörg Bartz
Account No.	605 24 50 00	905 94 65 00	Commercial Registry: Berlin-Charlottenburg HRB 64320
IBAN	DE77 1007 0000 0605 2450 00	DE50 1008 0000 0905 9465 00	VAT-No. DE 812 328 107
SWIFT	DEUT DE 33	DRES DE 33 100	

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Drawing of a representative product:



Material specifications:

Component	Raw material
1 Needle tube	Stainless Steel (SUS 304)
2 protective cap	Ethylene Polypropylene Copolymer
3 needle hub with wings (K)	Acrylonitrile Butadiene Styrene (ABS)
4 tubing	polyvinyl chloride polymer <i>plasticizer: DOP (DEHP)</i>
5 male conical fitting	Acrylonitrile Butadiene Styrene (ABS)
lubricant	silicone oil



- Sterilization:** by Ethylene Oxide (ETO)
- Latex:** KD-FLY scalp vein set is latex-free.
- Shelflife:** 5 years from the date of manufacture
dates of manufacture and expiry as well as the batch number are embossed / printed on both individual packages and inner boxes
- Storage:** Do not store at extreme temperature and humidity.
- Precautions for use:** Check the integrity of the individual package before use. Do not use if the package is damaged. For single use only. Dispose after single use to avoid risk of infection.

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Variants:**KD-FLY, luer slip, length of tube 30 cm tube**

Article no	Size of needle	
721803	18 G x 3/4"	1.20 x 19 mm
721902	19 G x 3/4"	1.10 x 19 mm
722008	20 G x 3/4"	0.90 x 19 mm
722107	21 G x 3/4"	0.80 x 19 mm
722206	22 G x 3/4"	0.70 x 19 mm
722305	23 G x 3/4"	0.60 x 19 mm
722404	24 G x 3/4"	0.55 x 19 mm
722503	25 G x 3/4"	0.50 x 19 mm
722602	26 G x 3/4"	0.45 x 19 mm
722701	27 G x 3/4"	0.40 x 19 mm

Packing data	pieces per	dimensions
individual packing (plastic package)	1	
inner box	100	
export carton	4000	

KD-FLY, luer lock, length of tube: 30 cm

Article no	Size of needle	
743164	18 G x 3/4"	1.20 x 19 mm
743171	19 G x 3/4"	1.10 x 19 mm
743188	20 G x 3/4"	0.90 x 19 mm
743195	21 G x 3/4"	0.80 x 19 mm
743201	22 G x 3/4"	0.70 x 19 mm
743218	23 G x 3/4"	0.60 x 19 mm
743225	24 G x 3/4"	0.55 x 19 mm
743232	25 G x 3/4"	0.50 x 19 mm
743249	26 G x 3/4"	0.45 x 19 mm
743256	27 G x 3/4"	0.40 x 19 mm

Packing data	pieces per	dimensions
individual packing (plastic package)	1	
inner box	50	0,175 x 0,12 x 0,86 m
export carton	2000	0,5 x 0,37 x 0,45 m

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KD-FLY, luer lock, blister packing

Article no	Size of needle	length of tube
741801	18 x 3/4"	30 cm
741900	19 x 3/4"	30 cm
742006	20 x 3/4"	30 cm
742105	21 x 3/4"	30 cm
742204	22 x 3/4"	30 cm
742303	23 x 3/4"	30 cm
742402	24 x 3/4"	30 cm
742501	25 x 3/4"	30 cm
742525	25 x 3/4"	60 cm
742549	25 x 3/8"	60 cm
742563	25 x 3/8"	90 cm
742600	26 x 3/4"	30 cm
742709	27 x 3/4"	30 cm
742723	27 x 3/8"	30 cm
742747	27 x 3/4"	60 cm
742761	27 x 3/8"	60 cm

KD-FLY, luer slip

Article no	Size of needle	length of tube
742785	18 x 3/4"	30 cm
742792	19 x 3/4"	30 cm
742808	20 x 3/4"	30 cm
742815	21 x 3/4"	30 cm
742822	22 x 3/4"	30 cm
742839	23 x 3/4"	30 cm
742846	24 x 3/4"	30 cm
742853	25 x 3/4"	30 cm
742860	25 x 3/4"	60 cm
742877	25 x 3/8"	60 cm
742884	25 x 3/8"	90 cm
742891	26 x 3/4"	30 cm
742907	27 x 3/4"	30 cm
742914	27 x 3/8"	30 cm
742921	27 x 3/4"	60 cm
742938	27 x 3/8"	60 cm

Packing data	pieces per	dimensions
individual packing (blister package)	1	0,063 x 0,083 m
inner box	50	0,175 x 0,12 x 0,86 m
export carton	2000	0,5 x 0,37 x 0,45 m

Issue: 21.02.2011
Revision: 1

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