



KD MEDICAL GMBH HOSPITAL PRODUCTS®

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

Summary Essential Technical Data - KD-FINE sterile hypodermic needles for single use

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

Product: Needles hypodermic
(Sterile hypodermic needles for single use)

Brand: KD-FINE

UMDNS code: 12-745

Risk Class: IIa according to Annex IX, rule 6 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-FINE sterile hypodermic needles for single use are medical devices consisting of hub, needle tube and protective cap. Hypodermic needles are used in connection with disposable syringes or disposable infusion / transfusion sets for medicine injection / infusion or blood collection.

KD-FINE's needle tube is made of stainless steel for the puncture of skin, muscle tissue and veins to allow injection of medicine, transfusion or withdrawal of blood.

One end of the hypodermic needle is a 6 % luer lock connector suitable for connection to syringes or to infusion / transfusion sets.

Sterilized by Ethylene Oxide, KD-FINE hypodermic needles are non-toxic, pyrogen-free, easy to use and characterized through their sharpness.

Usage of disposable medical devices can avoid cross-infections between patients.

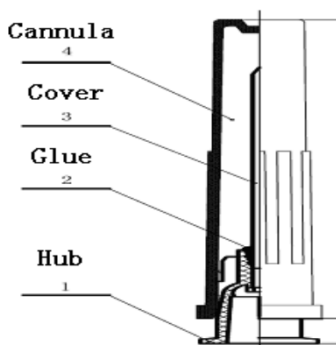
Bank	Deutsche Bank AG, Berlin	Commerzbank AG, Berlin	Registered Office: Berlin
Bank Code	100 700 00	100 800 00	Managing Director: Jörg Bartz
Account No.	605 24 50 00	905 94 65 00	Commercial Registry: Berlin-
IBAN	DE77 1007 0000 0605 2450 00	DE50 1008 0000 0905 9465 00	Charlottenburg HRB 64320
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Drawing:



Sterilization: by Ethylene Oxide (ETO)

Latex: KD-FINE hypodermic needles are 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

Material specifications:

Component	Raw material
1 Hub	Polypropylene PPH1500
2 Adhesive	Epoxy Glue
3 Cover	Polypropylene PP R370Y
4 Cannula	Stainless Steel SUS 304
Lubricant	Silicone oil

Packing data:	individual package	inner box (cardboard)	Export carton (cardboard)
for needles <= 50 mm length	Blister (PP film / paper) <i>(the film is mainly made of PP, it does not contain PVC)</i>	100 pieces	5000 pieces
for needles > 50 mm length	Blister (PP film / paper) <i>(the film is mainly made of PP, it does not contain PVC)</i>	50 pieces	2000 pieces

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.

Re-use of single-use devices creates a potential risk of 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.

Usage of KD-FINE sterile hypodermic needles for drug withdrawal out of vials might lead to punching of pieces of the rubber plug with subsequent contamination of the medicine.

Discard after single use to avoid risk of infection.

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Variants:

Disposable hypodermic needle KD-FINE, sterile, luer lock					
Article no	Size		Specification	Class	UMDNS no
908419	14 G x 8"	2,10 x 200 mm		Ila	12-745
900390	14 G x 1 1/2"	2,10 x 40 mm	SB / BC (short bevel)	Ila	12-745
900406	14 G x 3 1/5"	2,10 x 80 mm	SB / BC (short bevel)	Ila	12-745
914076	14 G x 3 1/5"	2,10 x 80 mm	SB / BC (short bevel)	Ila	12-745
900413	15 G x 1 1/2"	1,80 x 40 mm	SB / BC (short bevel)	Ila	12-745
900420	16 G x 1"	1,60 x 25 mm	SB / BC (short bevel)	Ila	12-745
900437	16 G x 1 1/2"	1,60 x 40 mm	SB / BC (short bevel)	Ila	12-745
900062	18 G x 1 1/2"	1,20 x 40 mm	SB / BC (short bevel)	Ila	12-745
908365	18 G x 1 1/2"	1,20 x 40 mm	LB / BL (long bevel)	Ila	12-745
914083	18 G x 1 1/2"	1,20 x 40 mm	SB / BC (short bevel)	Ila	12-745
914090	18 G x 2"	1,20 x 50 mm	SB / BC (short bevel)	Ila	12-745
900444	18 G x 2"	1,20 x 50 mm	SB / BC (short bevel)	Ila	12-745
900451	19 G x 1"	1,10 x 25 mm	SB / BC (short bevel)	Ila	12-745
900468	19 G x 1 1/4"	1,10 x 30 mm	SB / BC (short bevel)	Ila	12-745
900109	19 G x 1 1/2"	1,1 x 40 mm	SB / BC (short bevel)	Ila	12-745
908389	19 G x 1 1/2"	1,1 x 40 mm	LB / BL (long bevel)	Ila	12-745
900475	19 G x 2"	1,10 x 50 mm	SB / BC (short bevel)	Ila	12-745
900123	20 G x 1 "	0,90 x 25 mm	LB / BL (long bevel)	Ila	12-745
900130	20 G x 1 1/2"	0,90 x 40 mm	LB / BL (long bevel)	Ila	12-745
914106	20 G x 1 1/2"	0,90 x 40 mm	SB / BC (short bevel)	Ila	12-745
900482	20 G x 2"	0,90 x 50 mm	LB / BL (long bevel)	Ila	12-745
900499	20 G x 2 3/4"	0,90 x 70 mm	LB / BL (long bevel)	Ila	12-745
900505	21 G x 5/8"	0,80 x 16 mm	LB / BL (long bevel)	Ila	12-745
900512	21 G x 7/8"	0,80 x 22 mm	LB / BL (long bevel)	Ila	12-745
900529	21 G x 1"	0,80 x 25 mm	LB / BL (long bevel)	Ila	12-745
900192	21 G x 1 1/2"	0,80 x 40 mm	LB / BL (long bevel)	Ila	12-745
900536	21 G x 2"	0,80 x 50 mm	LB / BL (long bevel)	Ila	12-745
900543	21 G x 3 1/5"	0,80 x 80 mm	LB / BL (long bevel)	Ila	12-745
900550	21 G x 4 4/5"	0,80 x 120 mm	LB / BL (long bevel)	Ila	12-745
900567	22 G x 5/8"	0,70 x 16 mm	LB / BL (long bevel)	Ila	12-745
900574	22 G x 1"	0,70 x 25 mm	LB / BL (long bevel)	Ila	12-745
900581	22 G x 1 1/4	0,70 x 30 mm	LB / BL (long bevel)	Ila	12-745
900260	22 G x 1 1/2"	0,70 x 40 mm	LB / BL (long bevel)	Ila	12-745
900598	22 G x 2"	0,70 x 50 mm	LB / BL (long bevel)	Ila	12-745
900284	23 G x 1 "	0,60 x 25 mm	LB / BL (long bevel)	Ila	12-745
900291	23 G x 1 1/4"	0,60 x 30 mm	LB / BL (long bevel)	Ila	12-745
900604	23 G x 1 1/2"	0,60 x 40 mm	LB / BL (long bevel)	Ila	12-745
900611	23 G x 2 2/5"	0,60 x 60 mm	LB / BL (long bevel)	Ila	12-745
900628	23 G x 3 1/5"	0,60 x 80 mm	LB / BL (long bevel)	Ila	12-745
900635	24 G x 1"	0,55 x 25 mm	LB / BL (long bevel)	Ila	12-745
900345	25 G x 5/8"	0,50 x 16 mm	LB / BL (long bevel)	Ila	12-745
908006	25 G x 3/4"	0,50 x 19 mm	LB / BL (long bevel)	Ila	12-745
900642	25 G x 1"	0,50 x 25 mm	LB / BL (long bevel)	Ila	12-745
900659	25 G x 1 1/2"	0,50 x 40 mm	LB / BL (long bevel)	Ila	12-745
900666	26 G x 3/8"	0,45 x 10 mm	LB / BL (long bevel)	Ila	12-745
900383	26 G x 1/2"	0,45 x 12 mm	LB / BL (long bevel)	Ila	12-745
908327	26 G x 1/2"	0,45 x 13 mm	LB / BL (long bevel)	Ila	12-745
900673	26 G x 5/8"	0,45 x 16 mm	LB / BL (long bevel)	Ila	12-745
900680	26 G x 7/8"	0,45 x 22 mm	LB / BL (long bevel)	Ila	12-745
900697	26 G x 1"	0,45 x 25 mm	LB / BL (long bevel)	Ila	12-745
900703	27 G x 1/2"	0,40 x 12 mm	LB / BL (long bevel)	Ila	12-745
870426	27 G x 1/2"	0,40 x 13 mm	LB / BL (long bevel)	Ila	12-745
900710	27 G x 3/4"	0,40 x 18 mm	LB / BL (long bevel)	Ila	12-745
900727	27 G x 4/5"	0,40 x 20 mm	LB / BL (long bevel)	Ila	12-745
900734	27 G x 1"	0,40 x 25 mm	LB / BL (long bevel)	Ila	12-745
904404	27 G x 1 1/2"	0,40 x 40 mm	LB / BL (long bevel)	Ila	12-745
900741	29 G x 1/2"	0,33 x 12 mm	LB / BL (long bevel)	Ila	12-745
900758	30 G x 1/2"	0,29 x 12 mm	LB / BL (long bevel)	Ila	12-745

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