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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

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 infusion or blood collection.

To achieve above-mentioned functions, the product should have the following functions:
puncture, connection and transfusion

Puncture: the hypodermic 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.

Connection: One end of the hypodermic needle is a 6 % luer slip connector or 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.

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DE50 1008 0000 0905 9465 00
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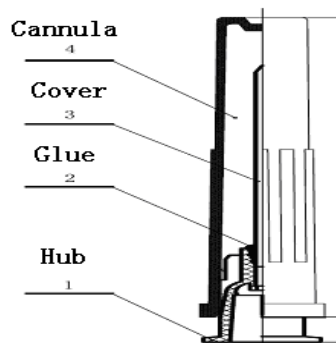
Registered Office: Berlin
Managing Director: Jörg Bartz
Commercial Registry: Berlin-Charlottenburg HRB 64320
VAT-No. DE 812 328 107

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Drawing:



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

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

Packing data:

*for needles
≤ 50 mm
length
for needles
> 50 mm
length*

	individual package	inner box	Export carton
Blister (film / paper)		100 pieces	5000 pieces
Blister (film / paper)		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. Discard after single use to avoid risk of infection.

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Variants:

Disposable hypodermic needle KD-FINE, sterile, luer					
Article no	Size		Specification	Class	UMDNS no
908419	18 G x 8"	1,2 x 200 mm	SB / BC (short bevel)	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
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
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
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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