

## EU Declaration of Conformity

### according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

Medical Device	KD-FINE® hypodermic needles; KD-FINE® SAFETY hypodermic needles
Product code/ catalogue number	see Annex 1
Basic UDI-DI according to Part C of Annex VI	4031881G10-01IlaKB
Intended Purpose	<p>KD-FINE® and KD-FINE® SAFETY hypodermic needles are medical devices intended for tissue penetration in order to provide a channel for injections or blood, body liquid or cell collection.</p> <p>Indications:</p> <ul style="list-style-type: none"> <li>• Intradermal, subcutaneous, intramuscular, intravenous, intraarticular and other soft tissue injections</li> <li>• blood / body liquid / cell collection</li> </ul>
Classification according to Annex VIII	Ila

Manufacturer	KD Medical GmbH Hospital Products Charlottenstrasse 65 10117 Berlin, Germany
Single Registration Number of manufacturer according to Article 31	DE-MF-000006773
Authorised Representative	Not applicable
Single Registration Number of Authorised Representative according to Article 31	Not applicable

We hereby declare, on our sole responsibility, the conformity of the abovementioned medical device(s) in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

We hereby ensure that the medical devices that are covered by the present declaration are in conformity with Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Applied Common Specifications (CS) - None

Notified Body	TÜV SÜD Product Service GmbH, identification number 0123
Conformity assessment procedure performed	For class Ila Medical Devices Annex IX
Certificate(s) issued	No. G10 037875 0048 Rev. 00 valid until 2029-01-17
CE marking since	Since 2002 according to Directive 93/42/EWG and since 01.2024 according to Regulation (EU) 2017/745
Validity of this EU Declaration of Conformity	2029-01-17

Signed on behalf of KD Medical GmbH Hospital Products

Dr. Andreas Pachten

Berlin, 2024-05-21



Person responsible for regulatory compliance – Product Conformity

Place, Date

Signature

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Annex 1: Article List

Article numbers KD-FINE® Hypodermic Needles, PO B05

Article no KDM	Size		Bevel	Wall thickness (ISO 9626)
910832	14 G x 8"	2,10 x 200 mm	SB / BC (short bevel)	ETW
900390	14 G x 1 1/2"	2,10 x 40 mm	SB / BC (short bevel)	ETW
900406	14 G x 3 1/5"	2,10 x 80 mm	SB / BC (short bevel)	ETW
900413	15 G x 1 1/2"	1,80 x 40 mm	SB / BC (short bevel)	TW
900420	16 G x 1"	1,60 x 25 mm	SB / BC (short bevel)	TW
900437	16 G x 1 1/2"	1,60 x 40 mm	SB / BC (short bevel)	TW
900062	18 G x 1 1/2"	1,20 x 40 mm	SB / BC (short bevel)	TW
908365	18 G x 1 1/2"	1,20 x 40 mm	LB / BL (long bevel)	TW
900444	18 G x 2"	1,20 x 50 mm	SB / BC (short bevel)	TW
908419	18 G x 8"	1,20 x 200 mm	SB / BC (short bevel)	TW
900451	19 G x 1"	1,10 x 25 mm	SB / BC (short bevel)	TW
900468	19 G x 1 1/4"	1,10 x 30 mm	SB / BC (short bevel)	TW
900109	19 G x 1 1/2"	1,1 x 40 mm	SB / BC (short bevel)	TW
908389	19 G x 1 1/2"	1,1 x 40 mm	LB / BL (long bevel)	TW
900475	19 G x 2"	1,10 x 50 mm	SB / BC (short bevel)	TW
900123	20 G x 1 "	0,90 x 25 mm	LB / BL (long bevel)	TW
900130	20 G x 1 1/2"	0,90 x 40 mm	LB / BL (long bevel)	TW
900482	20 G x 2"	0,90 x 50 mm	LB / BL (long bevel)	TW
900499	20 G x 2 3/4"	0,90 x 70 mm	LB / BL (long bevel)	TW
900505	21 G x 5/8"	0,80 x 16 mm	LB / BL (long bevel)	TW
900512	21 G x 7/8"	0,80 x 22 mm	LB / BL (long bevel)	TW
900529	21 G x 1"	0,80 x 25 mm	LB / BL (long bevel)	TW
900192	21 G x 1 1/2"	0,80 x 40 mm	LB / BL (long bevel)	TW
900536	21 G x 2"	0,80 x 50 mm	LB / BL (long bevel)	TW
900543	21 G x 3 1/5"	0,80 x 80 mm	LB / BL (long bevel)	TW
900550	21 G x 4 4/5"	0,80 x 120 mm	LB / BL (long bevel)	TW
900567	22 G x 5/8"	0,70 x 16 mm	LB / BL (long bevel)	TW
900574	22 G x 1"	0,70 x 25 mm	LB / BL (long bevel)	TW
900581	22 G x 1 1/4"	0,70 x 30 mm	LB / BL (long bevel)	TW
900260	22 G x 1 1/2"	0,70 x 40 mm	LB / BL (long bevel)	TW
900598	22 G x 2"	0,70 x 50 mm	LB / BL (long bevel)	TW
900284	23 G x 1 "	0,60 x 25 mm	LB / BL (long bevel)	TW
900291	23 G x 1 1/4"	0,60 x 30 mm	LB / BL (long bevel)	TW
900604	23 G x 1 1/2"	0,60 x 40 mm	LB / BL (long bevel)	TW
900611	23 G x 2 2/5"	0,60 x 60 mm	LB / BL (long bevel)	TW
900628	23 G x 3 1/5"	0,60 x 80 mm	LB / BL (long bevel)	TW
900635	24 G x 1"	0,55 x 25 mm	LB / BL (long bevel)	RW
900345	25 G x 5/8"	0,50 x 16 mm	LB / BL (long bevel)	TW
908006	25 G x 3/4"	0,50 x 19 mm	LB / BL (long bevel)	TW
900642	25 G x 1"	0,50 x 25 mm	LB / BL (long bevel)	TW
900659	25 G x 1 1/2"	0,50 x 40 mm	LB / BL (long bevel)	TW
900666	26 G x 3/8"	0,45 x 10 mm	LB / BL (long bevel)	RW
900383	26 G x 1/2"	0,45 x 12 mm	LB / BL (long bevel)	RW
908327	26 G x 1/2"	0,45 x 13 mm	LB / BL (long bevel)	RW

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Article no KDM	Size		Bevel	Wall thickness (ISO 9626)
900673	26 G x 5/8"	0,45 x 16 mm	LB / BL (long bevel)	RW
900680	26 G x 7/8"	0,45 x 22 mm	LB / BL (long bevel)	RW
900697	26 G x 1"	0,45 x 25 mm	LB / BL (long bevel)	RW
900703	27 G x 1/2"	0,40 x 12 mm	LB / BL (long bevel)	RW
870426	27 G x 1/2"	0,40 x 13 mm	LB / BL (long bevel)	RW
900710	27 G x 3/4"	0,40 x 18 mm	LB / BL (long bevel)	RW
900727	27 G x 4/5"	0,40 x 20 mm	LB / BL (long bevel)	RW
900734	27 G x 1"	0,40 x 25 mm	LB / BL (long bevel)	RW
904404	27 G x 1 1/2"	0,40 x 40 mm	LB / BL (long bevel)	RW
900741	29 G x 1/2"	0,33 x 12 mm	LB / BL (long bevel)	RW
900758	30 G x 1/2"	0,30 x 12 mm	LB / BL (long bevel)	RW
910795	30 G x 1/4"	0,30 x 6 mm	LB / BL (long bevel)	RW
917008	30 G x 1/6"	0,30 x 4 mm	LB / BL (long bevel)	RW
917022	32 G x 1/6"	0,23 x 4 mm	LB / BL (long bevel)	TW

Article number KD-FINE® SAFETY hypodermic needles with needle protection device (Type 1), PO D36

Article no KDM	Size		Bevel	Wall thickness (ISO 9626)
912393S	18 G x 1"	1,20 x 25 mm	SB / BC (short bevel)	TW
911495S	18 G x 1 1/2"	1,20 x 40 mm	SB / BC (short bevel)	TW
911501S	18 G x 1 1/2"	1,20 x 40 mm	LB / BL (long bevel)	TW
911518S	18 G x 2"	1,20 x 50 mm	SB / BC (short bevel)	TW
911525S	19 G x 1"	1,10 x 25 mm	SB / BC (short bevel)	TW
911532S	19 G x 1 1/4"	1,10 x 30 mm	SB / BC (short bevel)	TW
911549S	19 G x 1 1/2"	1,1 x 40 mm	SB / BC (short bevel)	TW
911556S	19 G x 1 1/2"	1,1 x 40 mm	LB / BL (long bevel)	TW
911563S	19 G x 2"	1,10 x 50 mm	SB / BC (short bevel)	TW
911570S	20 G x 1"	0,90 x 25 mm	LB / BL (long bevel)	TW
911587S	20 G x 1 1/2"	0,90 x 40 mm	LB / BL (long bevel)	TW
911594S	20 G x 2"	0,90 x 50 mm	LB / BL (long bevel)	TW
911600S	21 G x 5/8"	0,80 x 16 mm	LB / BL (long bevel)	TW
911617S	21 G x 7/8"	0,80 x 22 mm	LB / BL (long bevel)	TW
911624S	21 G x 1"	0,80 x 25 mm	LB / BL (long bevel)	TW
911631S	21 G x 1 1/2"	0,80 x 40 mm	LB / BL (long bevel)	TW
911648S	21 G x 2"	0,80 x 50 mm	LB / BL (long bevel)	TW
911655S	22 G x 5/8"	0,70 x 16 mm	LB / BL (long bevel)	TW
911662S	22 G x 1"	0,70 x 25 mm	LB / BL (long bevel)	TW
911679S	22 G x 1 1/4"	0,70 x 30 mm	LB / BL (long bevel)	TW
911686S	22 G x 1 1/2"	0,70 x 40 mm	LB / BL (long bevel)	TW
911693S	22 G x 2"	0,70 x 50 mm	LB / BL (long bevel)	TW
912430S	23 G x 5/8"	0,60 x 16 mm	LB / BL (long bevel)	TW
911709S	23 G x 1"	0,60 x 25 mm	LB / BL (long bevel)	TW
911716S	23 G x 1 1/4"	0,60 x 30 mm	LB / BL (long bevel)	TW
911723S	23 G x 1 1/2"	0,60 x 40 mm	LB / BL (long bevel)	TW
911730S	24 G x 1"	0,55 x 25 mm	LB / BL (long bevel)	RW

**EU Declaration of Conformity**  
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Article no KDM	Size		Bevel	Wall thickness (ISO 9626)
911747S	25 G x 5/8"	0,50 x 16 mm	LB / BL (long bevel)	TW
911754S	25 G x 3/4"	0,50 x 19 mm	LB / BL (long bevel)	TW
911761S	25 G x 1"	0,50 x 25 mm	LB / BL (long bevel)	TW
911778S	25 G x 1 1/2"	0,50 x 40 mm	LB / BL (long bevel)	TW
911785S	26 G x 3/8"	0,45 x 10 mm	LB / BL (long bevel)	RW
911792S	26 G x 1/2"	0,45 x 12 mm	LB / BL (long bevel)	RW
911808S	26 G x 1/2"	0,45 x 13 mm	LB / BL (long bevel)	RW
911815S	26 G x 5/8"	0,45 x 16 mm	LB / BL (long bevel)	RW
911822S	26 G x 7/8"	0,45 x 22 mm	LB / BL (long bevel)	RW
911839S	26 G x 1"	0,45 x 25 mm	LB / BL (long bevel)	RW
911846S	27 G x 1/2"	0,40 x 12 mm	LB / BL (long bevel)	RW
911853S	27 G x 1/2"	0,40 x 13 mm	LB / BL (long bevel)	RW
912454S	27 G x 5/8"	0,40 x 16 mm	LB / BL (long bevel)	RW
911860S	27 G x 3/4"	0,40 x 18 mm	LB / BL (long bevel)	RW
911877S	27 G x 4/5"	0,40 x 20 mm	LB / BL (long bevel)	RW
911884S	27 G x 1"	0,40 x 25 mm	LB / BL (long bevel)	RW
911891S	27 G x 1 1/2"	0,40 x 40 mm	LB / BL (long bevel)	RW
912478S	28 G x 1/2"	0,36 x 12 mm	LB / BL (long bevel)	TW
911907S	29 G x 1/2"	0,33 x 12 mm	LB / BL (long bevel)	RW
911914S	30 G x 1/2"	0,30 x 12 mm	LB / BL (long bevel)	RW
912416S	31 G x 5/16"	0,25 x 8 mm	LB / BL (long bevel)	RW
912492S	31 G x 1/2"	0,25 x 12 mm	LB / BL (long bevel)	RW

Article number KD-FINE® SAFETY hypodermic needles with needle protection device (Type 1), PO E08

Article no KDM	Size		Bevel	Wall thickness (ISO 9626)
912393E	18 G x 1"	1,20 x 25 mm	SB / BC (short bevel)	TW
911495E	18 G x 1 1/2"	1,20 x 40 mm	SB / BC (short bevel)	TW
911501E	18 G x 1 1/2"	1,20 x 40 mm	LB / BL (long bevel)	TW
911518E	18 G x 2"	1,20 x 50 mm	SB / BC (short bevel)	TW
911525E	19 G x 1"	1,10 x 25 mm	SB / BC (short bevel)	TW
911532E	19 G x 1 1/4"	1,10 x 30 mm	SB / BC (short bevel)	TW
911549E	19 G x 1 1/2"	1,1 x 40 mm	SB / BC (short bevel)	TW
911556E	19 G x 1 1/2"	1,1 x 40 mm	LB / BL (long bevel)	TW
911563E	19 G x 2"	1,10 x 50 mm	SB / BC (short bevel)	TW
911570E	20 G x 1"	0,90 x 25 mm	LB / BL (long bevel)	TW
911587E	20 G x 1 1/2"	0,90 x 40 mm	LB / BL (long bevel)	TW
911594E	20 G x 2"	0,90 x 50 mm	LB / BL (long bevel)	TW
911600E	21 G x 5/8"	0,80 x 16 mm	LB / BL (long bevel)	TW
911617E	21 G x 7/8"	0,80 x 22 mm	LB / BL (long bevel)	TW
911624E	21 G x 1"	0,80 x 25 mm	LB / BL (long bevel)	TW
911631E	21 G x 1 1/2"	0,80 x 40 mm	LB / BL (long bevel)	TW
911648E	21 G x 2"	0,80 x 50 mm	LB / BL (long bevel)	TW
911655E	22 G x 5/8"	0,70 x 16 mm	LB / BL (long bevel)	TW
911662E	22 G x 1"	0,70 x 25 mm	LB / BL (long bevel)	TW
911679E	22 G x 1 1/4"	0,70 x 30 mm	LB / BL (long bevel)	TW

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Article no KDM	Size		Bevel	Wall thickness (ISO 9626)
911686E	22 G x 1 1/2"	0,70 x 40 mm	LB / BL (long bevel)	TW
911693E	22 G x 2"	0,70 x 50 mm	LB / BL (long bevel)	TW
912430E	23 G x 5/8 "	0,60 x 16 mm	LB / BL (long bevel)	TW
911709E	23 G x 1 "	0,60 x 25 mm	LB / BL (long bevel)	TW
911716E	23 G x 1 1/4"	0,60 x 30 mm	LB / BL (long bevel)	TW
911723E	23 G x 1 1/2"	0,60 x 40 mm	LB / BL (long bevel)	TW
911730E	24 G x 1"	0,55 x 25 mm	LB / BL (long bevel)	RW
911747E	25 G x 5/8"	0,50 x 16 mm	LB / BL (long bevel)	TW
911754E	25 G x 3/4"	0,50 x 19 mm	LB / BL (long bevel)	TW
911761E	25 G x 1"	0,50 x 25 mm	LB / BL (long bevel)	TW
911778E	25 G x 1 1/2"	0,50 x 40 mm	LB / BL (long bevel)	TW
911785E	26 G x 3/8"	0,45 x 10 mm	LB / BL (long bevel)	RW
911792E	26 G x 1/2"	0,45 x 12 mm	LB / BL (long bevel)	RW
911808E	26 G x 1/2"	0,45 x 13 mm	LB / BL (long bevel)	RW
911815E	26 G x 5/8"	0,45 x 16 mm	LB / BL (long bevel)	RW
911822E	26 G x 7/8"	0,45 x 22 mm	LB / BL (long bevel)	RW
911839E	26 G x 1"	0,45 x 25 mm	LB / BL (long bevel)	RW
911846E	27 G x 1/2"	0,40 x 12 mm	LB / BL (long bevel)	RW
911853E	27 G x 1/2"	0,40 x 13 mm	LB / BL (long bevel)	RW
912454E	27 G x 5/8"	0,40 x 16 mm	LB / BL (long bevel)	RW
911860E	27 G x 3/4"	0,40 x 18 mm	LB / BL (long bevel)	RW
911877E	27 G x 4/5"	0,40 x 20 mm	LB / BL (long bevel)	RW
911884E	27 G x 1"	0,40 x 25 mm	LB / BL (long bevel)	RW
911891E	27 G x 1 1/2"	0,40 x 40 mm	LB / BL (long bevel)	RW
912478E	28 G x 1/2"	0,36 x 12 mm	LB / BL (long bevel)	TW
911907E	29 G x 1/2"	0,33 x 12 mm	LB / BL (long bevel)	RW
911914E	30 G x 1/2"	0,30 x 12 mm	LB / BL (long bevel)	RW
912416E	31 G x 5/16"	0,25 x 8 mm	LB / BL (long bevel)	RW
912492E	31 G x 1/2"	0,25 x 12 mm	LB / BL (long bevel)	RW

KD-FINE® SAFETY, hypodermic needles with needle protection device (T type 2), PO E63

Article no KDM	Size		Bevel	Wall thickness (ISO 9626)
912393B	18 G x 1"	1,20 x 25 mm	SB / BC (short bevel)	TW
911495B	18 G x 1 1/2"	1,20 x 40 mm	SB / BC (short bevel)	TW
911501B	18 G x 1 1/2"	1,20 x 40 mm	LB / BL (long bevel)	TW
911518B	18 G x 2"	1,20 x 50 mm	SB / BC (short bevel)	TW
911525B	19 G x 1"	1,10 x 25 mm	SB / BC (short bevel)	TW
911532B	19 G x 1 1/4"	1,10 x 30 mm	SB / BC (short bevel)	TW
911549B	19 G x 1 1/2"	1,1 x 40 mm	SB / BC (short bevel)	TW
911556B	19 G x 1 1/2"	1,1 x 40 mm	LB / BL (long bevel)	TW
911563B	19 G x 2"	1,10 x 50 mm	SB / BC (short bevel)	TW
911570B	20 G x 1 "	0,90 x 25 mm	LB / BL (long bevel)	TW
911587B	20 G x 1 1/2"	0,90 x 40 mm	LB / BL (long bevel)	TW
911594B	20 G x 2"	0,90 x 50 mm	LB / BL (long bevel)	TW
911600B	21 G x 5/8"	0,80 x 16 mm	LB / BL (long bevel)	TW

**EU Declaration of Conformity**  
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**and of the Council of 5 April 2017 on Medical Devices**

Article no KDM	Size		Bevel	Wall thickness (ISO 9626)
911617B	21 G x 7/8"	0,80 x 22 mm	LB / BL (long bevel)	TW
911624B	21 G x 1"	0,80 x 25 mm	LB / BL (long bevel)	TW
911631B	21 G x 1 1/2"	0,80 x 40 mm	LB / BL (long bevel)	TW
911648B	21 G x 2"	0,80 x 50 mm	LB / BL (long bevel)	TW
911655B	22 G x 5/8"	0,70 x 16 mm	LB / BL (long bevel)	TW
911662B	22 G x 1"	0,70 x 25 mm	LB / BL (long bevel)	TW
911679B	22 G x 1 1/4"	0,70 x 30 mm	LB / BL (long bevel)	TW
911686B	22 G x 1 1/2"	0,70 x 40 mm	LB / BL (long bevel)	TW
911693B	22 G x 2"	0,70 x 50 mm	LB / BL (long bevel)	TW
912430B	23 G x 5/8 "	0,60 x 16 mm	LB / BL (long bevel)	TW
911709B	23 G x 1 "	0,60 x 25 mm	LB / BL (long bevel)	TW
911716B	23 G x 1 1/4"	0,60 x 30 mm	LB / BL (long bevel)	TW
911723B	23 G x 1 1/2"	0,60 x 40 mm	LB / BL (long bevel)	TW
911730B	24 G x 1"	0,55 x 25 mm	LB / BL (long bevel)	RW
911747B	25 G x 5/8"	0,50 x 16 mm	LB / BL (long bevel)	TW
911754B	25 G x 3/4"	0,50 x 19 mm	LB / BL (long bevel)	TW
911761B	25 G x 1"	0,50 x 25 mm	LB / BL (long bevel)	TW
911778B	25 G x 1 1/2"	0,50 x 40 mm	LB / BL (long bevel)	TW
911785B	26 G x 3/8"	0,45 x 10 mm	LB / BL (long bevel)	RW
911792B	26 G x 1/2"	0,45 x 12 mm	LB / BL (long bevel)	RW
911808B	26 G x 1/2"	0,45 x 13 mm	LB / BL (long bevel)	RW
911815B	26 G x 5/8"	0,45 x 16 mm	LB / BL (long bevel)	RW
911822B	26 G x 7/8"	0,45 x 22 mm	LB / BL (long bevel)	RW
911839B	26 G x 1"	0,45 x 25 mm	LB / BL (long bevel)	RW
911846B	27 G x 1/2"	0,40 x 12 mm	LB / BL (long bevel)	RW
911853B	27 G x 1/2"	0,40 x 13 mm	LB / BL (long bevel)	RW
912454B	27 G x 5/8"	0,40 x 16 mm	LB / BL (long bevel)	RW
911860B	27 G x 3/4"	0,40 x 18 mm	LB / BL (long bevel)	RW
911877B	27 G x 4/5"	0,40 x 20 mm	LB / BL (long bevel)	RW
911884B	27 G x 1"	0,40 x 25 mm	LB / BL (long bevel)	RW
911891B	27 G x 1 1/2"	0,40 x 40 mm	LB / BL (long bevel)	RW
912478B	28 G x 1/2"	0,36 x 12 mm	LB / BL (long bevel)	TW
911907B	29 G x 1/2"	0,33 x 12 mm	LB / BL (long bevel)	RW
911914B	30 G x 1/2"	0,30 x 12 mm	LB / BL (long bevel)	RW