



KD MEDICAL GMBH HOSPITAL PRODUCTS®

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PF 060107	Charlottenstrasse 65
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KD Medical GmbH Hospital Products · Charlottenstrasse 65 · 10117 Berlin · Germany

## Declaration of conformity

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

**Name of the product:** Disposables for Anaesthesia and Respiration  
(specifications see attachment) Disposable Anaesthesia Needles -  
Spinal needles (with and without introducer needle)

We herewith declare in our own responsibility that the above-mentioned product(s) meet(s) the provisions of the Council Directive 93/42/EEC of 14th June 1993 concerning medical devices, as amended by Council Directive 2007/47/EC.  
All supporting documentation is retained under the premises of the manufacturer (QC department).

**Referenced standard(s) or normative documents:** indicated in the related "List of provisions and standards applied held by the manufacturer as part of the technical documentation

**Conformity assessment route:** - full quality assurance system according to Annex II excluding (-  
- design examination according to Annex II (4)  
of the Council Directive mentioned above

**Classification:** according to Annex IX of the Council Directive mentioned above Class III (rule 6, third bullet)

**Notified Body:** TÜV SÜD Product Service GmbH  
(Name, address, identification no) Ridlerstraße 65  
80339 München, Germany  
Identification no: 0123

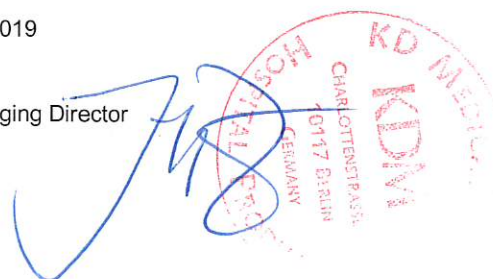
**EC certificate(s):** G1 037875 0044 Rev.00, G7 037875 0043 Rev.00

**EC certificate(s) valid until:** 26.05.2024, 15.08.2023

**Place, date of issue of this declaration:** Berlin, 10.07.2019

**Name, title and signature of authorized person:** J. Bartz, Managing Director

**This Declaration is valid until its next revision.**



Bank	Deutsche Bank AG, Berlin
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Commerzbank AG, Berlin
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DE50 1008 0000 0905 9465 00
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Registered Office: Berlin  
Managing Director: Jörg Bartz  
Commercial Registry: Berlin-  
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**Attachment to Declaration of conformity  
G7-01-8, revision 0, dated 10.07.2019**

**KD-FINE®, spinal needles, Quincke**

Article no	Size		Dimension introducer needle	Risk class	UMDNS code
900840	18 G x 3"	1.20 x 75 mm		III	12-753
900857	18 G x 3 1/2"	1.20 x 88 mm		III	12-753
900871	19 G x 1 1/2"	1.10 x 40 mm		III	12-753
900864	19 G x 3 1/2"	1.10 x 88 mm		III	12-753
900888	20 G x 3"	0.90 x 75 mm		III	12-753
900895	20 G x 3 1/2"	0.90 x 88 mm		III	12-753
901199	20 G x 3 1/2"	0.90 x 90 mm		III	12-753
901069	21 G x 3 1/2"	0.80 x 88 mm		III	12-753
900918	22 G x 1 1/2"	0.70 x 40 mm		III	12-753
913994	22 G x 2 1/2"	0.70 x 63 mm		III	12-753
901021	22 G x 3"	0.70 x 75 mm		III	12-753
900901	22 G x 3 1/2"	0.70 x 88 mm		III	12-753
901212	22 G x 3 1/2"	0.70 x 90 mm		III	12-753
910856	22 G x 4 3/4"	0.70 x 120 mm		III	12-753
901083	23 G x 3 1/2"	0.60 x 88 mm		III	12-753
901045	24 G x 3 1/2"	0.55 x 88 mm		III	12-753
910870	25 G x 2"	0.50 x 50 mm		III	12-753
910887	25 G x 3"	0.50 x 75 mm		III	12-753
900925	25 G x 3 1/2"	0.50 x 88 mm		III	12-753
910894	25 G x 4 3/4"	0.50 x 120 mm		III	12-753
910924	26 G x 2"	0.45 x 50 mm		III	12-753
901106	26 G x 3 1/2"	0.45 x 88 mm		III	12-753
910931	26 G x 4 3/4"	0.45 x 120 mm		III	12-753
910948	27 G x 2"	0.40 x 50 mm		III	12-753
901120	27 G x 3 1/2"	0.40 x 88 mm		III	12-753
910955	27 G x 4 3/4"	0.40 x 120 mm		III	12-753

**KD-FINE®, spinal needles, Pencil Point**

Article no	Size		Dimension introducer needle	Risk class	UMDNS code
901472	18 G x 3 1/2"	1.20 x 88 mm		III	12-753
901489	19 G x 3 1/2"	1.10 x 88 mm		III	12-753
901496	20 G x 3 1/2"	0.90 x 88 mm		III	12-753
901502	21 G x 3 1/2"	0.80 x 88 mm		III	12-753
901519	22 G x 3 1/2"	0.70 x 88 mm		III	12-753
910979	22 G x 4 3/4"	0.70 x 120 mm		III	12-753
901526	23 G x 3 1/2"	0.60 x 88 mm		III	12-753
901533	24 G x 3 1/2"	0.55 x 88 mm		III	12-753
910993	25 G x 2"	0.50 x 50 mm		III	12-753
911006	25 G x 3"	0.50 x 75 mm		III	12-753
901540	25 G x 3 1/2"	0.50 x 88 mm		III	12-753
911013	25 G x 4 3/4"	0.50 x 120 mm		III	12-753
911044	26 G x 2"	0.45 x 50 mm		III	12-753
901632	26 G x 3 1/2"	0.45 x 88 mm		III	12-753
911051	26 G x 4 3/4"	0.45 x 120 mm		III	12-753
911068	27 G x 2"	0.40 x 50 mm		III	12-753
901649	27 G x 3 1/2"	0.40 x 88 mm		III	12-753
911075	27 G x 4 3/4"	0.40 x 120 mm		III	12-753

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**KD-FINE®, spinal needles, Quincke, with introducer (guide) needle**

Article no	Size		Dimension introducer needle	Risk class	UMDNS code
910672	22 G x 4 1/8 "	0.70 x 105 mm	19G x 1 1/4" (1.10 x 30 mm)	III	12-753
901205	22 G x 4 4/5"	0.70 x 120 mm	19G x 1 1/2" (1.10 x 38 mm)	III	12-753
901243	24 G x 3 1/2"	0.55 x 90 mm	20G x 1 1/4" (0.90 x 30 mm)	III	12-753
910634	24 G x 4 1/8 "	0.55 x 105 mm	20G x 1 1/4" (0.90 x 30 mm)	III	12-753
910641	24 G x 4 4/5"	0.55 x 120 mm	20G x 1 1/2" (0.90 x 38 mm)	III	12-753
901144	25 G x 3 1/2"	0.50 x 88 mm	21G x 1 1/2" (0.80 x 38 mm)	III	12-753
911099	25 G x 4"	0.50 x 103 mm	21G x 1 1/2" (0.80 x 38 mm)	III	12-753
901458	25 G x 4 1/8 "	0.50 x 105 mm	21G x 1 1/2" (0.80 x 38 mm)	III	12-753
901267	25 G x 4 4/5"	0.50 x 120 mm	21G x 1 1/2" (0.80 x 38 mm)	III	12-753
901151	26 G x 3 1/2"	0.45 x 88 mm	21G x 1 1/2" (0.80 x 38 mm)	III	12-753
901229	26 G x 4 1/8"	0.45 x 105 mm	21G x 1 1/2" (0.80 x 38 mm)	III	12-753
901168	27 G x 3 1/2"	0.40 x 88 mm	22G x 1 1/2" (0.70 x 38 mm)	III	12-753
911105	27 G x 4"	0.40 x 103 mm	21G x 1 1/2" (0.80 x 38 mm)	III	12-753

**KD-FINE®, spinal needles, Pencil Point, with introducer (guide) needle**

Article no	Size		Dimension introducer needle	Risk class	UMDNS code
901236	22 G x 3 1/2"	0.70 x 88 mm	19G x 1 1/4" (1.10 x 30 mm)	III	12-753
910818	24 G x 3 1/2"	0.55 x 88 mm	20G x 1 1/2" (0.90 x 38 mm)	III	12-753
901175	25 G x 3 1/2"	0.50 x 88 mm	21G x 1 1/2" (0.80 x 38 mm)	III	12-753
911129	25 G x 4"	0.50 x 103 mm	21G x 1 1/2" (0.80 x 38 mm)	III	12-753
901182	26 G x 3 1/2"	0.45 x 88 mm	21 G x 1 1/2" (0.80 x 38 mm)	III	12-753
901441	27 G x 3 1/2"	0.40 x 88 mm	22 G x 1 1/2" (0.70 x 38 mm)	III	12-753
911136	27 G x 4"	0.40 x 103 mm	21G x 1 1/2" (0.80 x 38 mm)	III	12-753
901250	27 G x 4 4/5"	0.40 x 120 mm	22 G x 1 1/2" (0.70 x 38 mm)	III	12-753

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