



KD MEDICAL GMBH HOSPITAL PRODUCTS®

Postal Address	Office
PF 060107	Charlottenstrasse 65
10051 Berlin	10117 Berlin
Germany	Germany

Phone	+49-30-20 39 95 91/92
Fax	+49-30-20 39 95 99
E-mail	info@kdm-berlin.de
http	www.kdm-berlin.de

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: Pen needles

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: according to Annex II excluding (4) of the Council Directive mentioned above

Classification: according to Annex IX of the Council Directive mentioned above
Class IIa

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

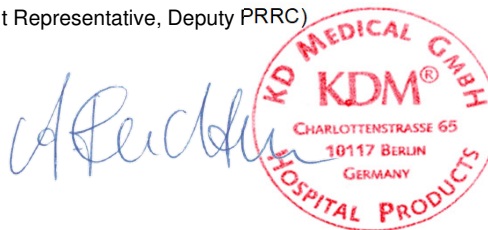
EC certificate(s): G1 037875 0044 Rev.01

EC certificate(s) valid until: 31.12.2028 (Confirmation Letter CL 037875 0054 Rev. 00)

Place, date of issue of this declaration: Berlin, 21.05.2024

Name, title and signature of authorized person: Dr. A. Pachten
(Quality Management Representative, Deputy PRRC)

This Declaration is valid until 31.12.2028 or its next revision.



Currency	USD and EUR	USD	EUR and PLN	Registered Office: Berlin
Bank	Deutsche Bank AG	Commerzbank AG	Commerzbank AG	Managing Directors:
Bank Code	100 700 00	100 800 00	100 800 00	Jörg Bartz, Katarzyna Kupczak
Account No.	605 24 50 00	0905 94 65 01	0905 94 65 00	Commercial Registry: Berlin-
IBAN	DE77 1007 0000 0605 2450 00	DE23 1008 0000 0905 9465 01	DE50 1008 0000 0905 9465 00	Charlottenburg HRB 64320
SWIFT	DEUT DE 33	DRES DE 33 100	DRES DE 33 100	VAT-No. DE 812 328 107



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Attachment to Declaration of conformity G1-18-8, revision 5, dated 21.05.2024

KD-PENOFINE, sterile pen needles for single use				
Article no	Specification		Risk class	UMDNS code
904206	0,36 x 12 mm	28G	Ila	12-745
904213	0,33 x 12 mm	29G	Ila	12-745
904220	0,33 x 12,7 mm	29G	Ila	12-745
904237	0,33 x 10 mm	29G	Ila	12-745
907009	0,33 x 8 mm	29G	Ila	12-745
907016	0,33 x 6 mm	29G	Ila	12-745
907023	0,30 x 12 mm	30G	Ila	12-745
907030	0,30 x 10 mm	30G	Ila	12-745
904244	0,30 x 8 mm	30G	Ila	12-745
904251	0,30 x 6 mm	30G	Ila	12-745
908303	0,25 x 12 mm	31G	Ila	12-745
904268	0,25 x 8 mm	31G	Ila	12-745
904275	0,25 x 6 mm	31G	Ila	12-745
904282	0,25 x 5 mm	31G	Ila	12-745
910719	0,23 x 4 mm	32G	Ila	12-745
914014	0,23 x 6 mm	32G	Ila	12-745
914021	0,23 x 8 mm	32G	Ila	12-745
910733	0,21 x 4 mm	33G	Ila	12-745
904206T	0,36 x 12 mm	28G	Ila	12-745
904213T	0,33 x 12 mm	29G	Ila	12-745
904220T	0,33 x 12,7 mm	29G	Ila	12-745
904237T	0,33 x 10 mm	29G	Ila	12-745
907009T	0,33 x 8 mm	29G	Ila	12-745
907016T	0,33 x 6 mm	29G	Ila	12-745
907023T	0,30 x 12 mm	30G	Ila	12-745
907030T	0,30 x 10 mm	30G	Ila	12-745
904244T	0,30 x 8 mm	30G	Ila	12-745
904251T	0,30 x 6 mm	30G	Ila	12-745
908303T	0,25 x 12 mm	31G	Ila	12-745
904268T	0,25 x 8 mm	31G	Ila	12-745
904275T	0,25 x 6 mm	31G	Ila	12-745
904282T	0,25 x 5 mm	31G	Ila	12-745
910719T	0,23 x 4 mm	32G	Ila	12-745
916124T	0,23 x 5 mm	32G	Ila	12-745
914014T	0,23 x 6 mm	32G	Ila	12-745
914021T	0,23 x 8 mm	32G	Ila	12-745
910733T	0,21 x 4 mm	33G	Ila	12-745

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SWIFT DEUT DE BB

USD
Commerzbank AG
100 800 00
0905 94 65 01
DE23 1008 0000 0905 9465 01
DRES DE FF 100

EUR and PLN
Commerzbank AG
100 800 00
0905 94 65 00
DE50 1008 0000 0905 9465 00
DRES DE FF 100

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Managing Directors:
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KD-PENOFINE SAFETY, sterile safety pen needles for single use				
Article no	Specification		Risk class	UMDNS code
919965	0,30 x 8 mm	30G	Ila	12-745
919972	0,30 x 6 mm	30G	Ila	12-745
920183	0,30 x 5 mm	30G	Ila	12-745
920190	0,30 x 4 mm	30G	Ila	12-745
919996	0,25 x 8 mm	31G	Ila	12-745
920008	0,25 x 6 mm	31G	Ila	12-745
920015	0,25 x 5 mm	31G	Ila	12-745
920220	0,25 x 4 mm	31G	Ila	12-745
920022	0,23 x 4 mm	32G	Ila	12-745
920039	0,23 x 6 mm	32G	Ila	12-745
920046	0,23 x 8 mm	32G	Ila	12-745



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