



KD MEDICAL GMBH HOSPITAL PRODUCTS®

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| Germany | Germany |

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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: Syringes Insulin

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.00

EC certificate(s) valid until: 26.05.2024

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

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

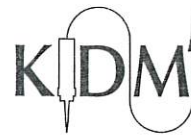
This Declaration is valid until its next revision.



Bank Deutsche Bank AG, Berlin
Bank Code 100 700 00
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IBAN DE77 1007 0000 0605 2450 00
SWIFT DEUT DE 33

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-Charlottenburg HRB 64320
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**Attachment to Declaration of conformity
G1-05-8, revision 0, dated 10.07.2019**

KD-JECT III, Syringes, Latex, 3-parts, Luer, 1ml, mounted needle

| Article no | Specification | Risk class | UMDNS code |
|------------|------------------------------------------------------------------------------------------------|------------|------------|
| 801345 | Syringes, 3-parts, Latex, Luer, 1ml, Insulin, U 100, mounted needle 27 G x 1/2" (0,40 x 12 mm) | Ila | 13-941 |
| 831373 | Syringes, 3-parts, Latex, Luer, 1ml, Insulin, U 100, mounted needle 29 G x 1/2" (0,33 x 12 mm) | Ila | 13-941 |
| 831700 | Syringes, 3-parts, Latex, Luer, 1ml, Insulin, U 100, mounted needle 26 G x 1/2" (0,45 x 12 mm) | Ila | 13-941 |
| 831724 | Syringes, 3-parts, Latex, Luer, 1ml, Insulin, U 100, mounted needle 30 G x 1/2" (0,30 x 13 mm) | Ila | 13-941 |
| 811344 | Syringes, 3-parts, Latex, Luer, 1ml, Insulin, U 40, mounted needle 26 G x 1/2" (0,45 x 12 mm) | Ila | 13-941 |
| 831380 | Syringes, 3-parts, Latex, Luer, 1ml, Insulin, U 40, mounted needle 27 G x 1/2" (0,40 x 12 mm) | Ila | 13-941 |
| 831397 | Syringes, 3-parts, Latex, Luer, 1ml, Insulin, U 40, mounted needle 29 G x 1/2" (0,33 x 12 mm) | Ila | 13-941 |

KD-JECT III, Syringes, Latex-free, 3-parts, Luer, 1ml, mounted needle

| Article no | Specification | Risk class | UMDNS code |
|------------|-----------------------------------------------------------------------------------------------------|------------|------------|
| 831755 | Syringes, 3-parts, Latex Free, Luer, 1ml, Insulin, U 100, mounted needle 29 G x 1/2" (0,33 x 12 mm) | Ila | 13-941 |
| 870600 | Syringes, 3-parts, Latex Free, Luer, 1ml, Insulin, U 100, mounted needle 27 G x 1/2" (0,40 x 12 mm) | Ila | 13-941 |
| 870624 | Syringes, 3-parts, Latex Free, Luer, 1ml, Insulin, U 100, without needle | Ila | 13-941 |
| 831762 | Syringes, 3-parts, Latex Free, Luer, 1ml, Insulin, U 40, mounted needle 29 G x 1/2" (0,33 x 12 mm) | Ila | 13-941 |
| 831779 | Syringes, 3-parts, Latex Free, Luer, 1ml, Insulin, U 40, mounted needle 27 G x 1/2" (0,40 x 13 mm) | Ila | 13-941 |

KD-JECT III, Syringes, Latex, 3-parts, UNIBODY, Luer, with integrated needle, Insulin

| Article no | Specification | Risk class | UMDNS code |
|------------|----------------------------------------------------------------------------------------------------------------------------------------|------------|------------|
| 870181 | Syringes, Latex, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U40, 29 G x 1/2" (0,33 x 12 mm), 10 per plastic bag | Ila | 13-941 |
| 870198 | Syringes, Latex, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U40, 30 G x 1/2" (0,30 x 12 mm), 10 per plastic bag | Ila | 13-941 |
| 870129 | Syringes, Latex, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U40, 29 G x 1/2" (0,33 x 12 mm), Blister | Ila | 13-941 |
| 870143 | Syringes, Latex, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U40, 30 G x 1/2" (0,30 x 12 mm), Blister | Ila | 13-941 |
| 870167 | Syringes, Latex, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U100, 29 G x 1/2" (0,33 x 12 mm), 10 per plastic bag | Ila | 13-941 |
| 870334 | Syringes, Latex, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U100, 30 G x 5/16" (0,30 x 8 mm), 10 per plastic bag | Ila | 13-941 |
| 870082 | Syringes, Latex, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U100, 29 G x 1/2" (0,33 x 12 mm), Blister | Ila | 13-941 |
| 870747 | Syringes, Latex, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U100, 30 G x 1/2" (0,30 x 12 mm), Blister | Ila | 13-941 |
| 873267 | Syringes, Latex, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U100, 30 G x 5/16" (0,30 x 8 mm), 1 per blister, latex | Ila | 13-941 |

KD-JECT III, Syringes, Latex-free, 3-parts, UNIBODY, Luer, with integrated needle, Insulin

| Article no | Specification | Risk class | UMDNS code |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------|------------|------------|
| 870174 | Syringes, Latex-free, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U100, 30 G x 1/2" (0,30 x 12 mm), 10 per plastic bag | Ila | 13-941 |
| 870228 | Syringes, Latex-free, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U100, 30 G x 1/2" (0,30 x 12 mm), 10 per plastic bag | Ila | 13-941 |
| 870303 | Syringes, Latex-free, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U100, 30 G x 5/16" (0,30 x 8 mm), 10 per plastic bag | Ila | 13-941 |
| 870105 | Syringes, Latex-free, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U100, 30 G x 1/2" (0,30 x 12,7 mm), Blister | Ila | 13-941 |
| 870204 | Syringes, Latex-free, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U100, 30 G x 1/2" (0,30 x 12 mm), Blister | Ila | 13-941 |
| 870501 | Syringes, Latex-free, 3-parts, Unibody, Luer, 0,3 ml, with integrated needle, Insulin, U100, 30 G x 5/16" (0,30 x 8 mm), Blister | Ila | 13-941 |
| 870518 | Syringes, Latex-free, 3-parts, Unibody, Luer, 0,5 ml, with integrated needle, Insulin, U100, 29 G x 1/2" (0,33 x 12,7 mm), Blister | Ila | 13-941 |
| 870525 | Syringes, Latex-free, 3-parts, Unibody, Luer, 0,5 ml, with integrated needle, Insulin, U100, 30 G x 5/16" (0,30 x 8 mm), Blister | Ila | 13-941 |
| 870532 | Syringes, Latex-free, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U100, 29 G x 1/2" (0,33 x 12,7 mm), Blister | Ila | 13-941 |
| 870549 | Syringes, Latex-free, 3-parts, Unibody, Luer, 1 ml, with integrated needle, Insulin, U100, 30 G x 5/16" (0,30 x 8 mm), Blister | Ila | 13-941 |