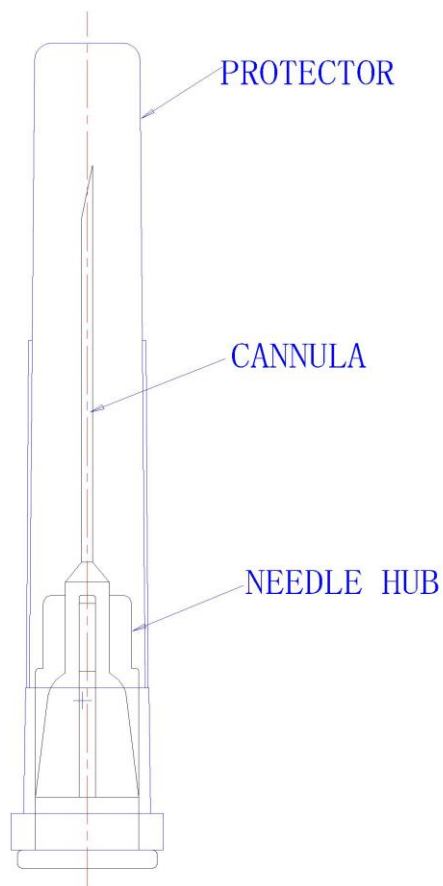


Jiangsu Zhengkang Medical Apparatus Co.,Ltd	No.: JSZK/CE-2010-04
Technical file	VERSION No.: A
Disposable hypodermic needle	Page: 1 of 4

1. Product description.

Disposable hypodermic needle, used for injection, skin test, phlebotomy and confecting of solutions and reagent, mainly used together with syringes and infusion sets, for single-use. Disposable sterile hypodermic needle is made up of needle hub, stainless cannula and protective cap.The needle hub and protective cap are mould-injected by PP, medical grade.

2. Technical drawing.



3. Product name and intended use.

Disposable hypodermic needle is suitable to use as hypodermic injection, skill test, blood collection and test the medicine solution.

Jiangsu Zhengkang Medical Apparatus Co.,Ltd	No.: JSZK/CE-2010-04
Technical file	VERSION No.: A
Disposable hypodermic needle	Page: 2 of 4

4. Classification.

According to the annex IX, rule 7, II a.

5. Certification route of the EC products.

According to the requirement of the MDD93/42/EEC, the route of the company to apply the EC marked products is according to annex V and VII.

6. Model and size.

The specification of disposable hypodermic needles: 0.3 (30G) 0.33 (29G) 0.36 (28G) 0.4 (27G) ; 0.45 (26G) ; 0.5 (25G) ; 0.55 (24G) ; 0.6 (23G) ; 0.7 (22G) ; 0.8 (21G) ; 0.9 (20G) ; 1.1 (19G) ; 1.2 (18G) ; 1.6 (16G)

7. Structure, material, performance.

Disposable hypodermic needle is used as hypodermic injection, skill test, blood collection and test the medicine solution. It is suitable to used with disposable syringes and infusion sets. For single use only.

Disposable hypodermic needle is combined by needle hub, stainless steel cannula and protector. The hub and protector are made by medical grade PP mould-injection. After biological testing, the hypodermic needle should be nonhemolysis, nontoxicity, nonagile, non urgent toxicity, nonintra dermal stimulus-respons, all physics, chemical and biology indication measure up.

8. Production environment and sterilization method.

All components should be in 100,000 class cleaning workshop from producing to assembling. The products should be sterilized by EO after finishing outer carton packing.

9. Description of all performance test

All performance test for the disposable hypodermic needle is according to the standard ISO7864:1993, the sampling basis is GB/2828.1-2003, physical performance, chemical performance, biological performance will be tested, the test results are qualified, comply with the standard requirement.

Chemical performance.

1)	Acidity and alkalinity	Difference of pH value between the test solution and blank solution ≤ 1
2)	Extractable metals	Extractable metal contents in the test solution $\leq 5\mu\text{g/ml}$,

Biological performance.

3)	Non bacteria	Shall be non bacteria
4)	Pyrogen	Shall be non pyrogenic
5)	Hemolysis	Shall be no hemolysis reaction
6)	Acute systemic toxicity	Shall be no acute systemic toxicity reaction
7)	Cytotoxicity	Reaction \leq I class
8)	Sensitization	Shall be no sensitization reaction
9)	Skin irritation	Shall be no skin irritation

Physical performance.

Jiangsu Zhengkang Medical Apparatus Co.,Ltd	No.: JSZK/CE-2010-04
Technical file	VERSION No.: A
Disposable hypodermic needle	Page: 3 of 4

10)	Needle cannula rigidity	Yield strength $\leq 0.45\text{mm}$
11)	Needle cannula tenacity	Shall not be broken if bend repeatedly in double direction
12)	Corrosion Resistance	Shall be with a good corrosion resistance
13)	Needle point	Shall be no hooks, no spurs
14)	Conical hub requirement	Should meet the requirement of GB/T1962-2001.
15)	Connection force	Shall not be detached between the hub and needle under a force of 34N
16)	Puncture force	Shall be sharp, penetration force $\leq 0.70\text{N}$
17)	Needle cannula channel	Shall be straight, clean, no foreign matters
18)	Needle appearance	Without any defects of hairy side, burr, injection flow and air bubble.
19)	Needle hub lumen	Shall be no particles and foreign matters in the lumen
20)	Needle cannula outer diameter	Nominal outer diameter $0.63\text{mm} \pm 0.02\text{mm}$
21)	Needle cannula length	$L = 25\text{mm} + 1.5\text{mm} / - 2.5\text{mm}$
22)	Lubricant	No small drops at the surface of the needle cannula
23)	Clean inside the cannula	Shall be clean, no foreign matters and dirty
24)	Hub color	Shall be dark blue
25)	Needle cannula straight in the hub	Needle cannula shall be straightly in the needle hub
26)	Needle hub and protector connect	Needle protector shall fit for the hub well, detach force $\leq 15\text{N}$
27)	Minimum cannula channel	Cannula channel shall be unobstructed,
28)	unit packing	Labelling shall comply with the requirement

Remark:

- the above test is take the 0.7mm needle as an example.
- the physical performance have to be tested for every batch.
- the acidity and alkalinity have to be tested for every batch.
- the pyrogen and bacteria have to be tested for every batch.

10. Applicable law and standard list.

1	ISO 13485:2003	Medical devices - Quality management systems - Requirements for regulatory purposes
2	MDD 93/42/EEC	Council Directive 93/42/EEC medical devices
3	EN ISO 14971:2007	Medical devices - Application of risk management to medical devices
4	EN 980:2008	Symbols for use in the labelling of medical devices
5	EN 1041:2008	Information supplied by the manufacturer of medical devices
6	EN ISO 11135-1:2007	Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
7	EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems;
8	EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices – Part 2: validation requirements for forming, sealing and assembly processes,
9	EN ISO10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
10	ISO 7886-1: 1993	Disposable hypodermic needle – part 1: manual syringe
11	ISO 7864:1993	Sterile hypodermic needles for single use
12	GB/T2828.1-2003	Sampling procedures for inspection by attributes - Part1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection