



## Disposable needles

### General description of the products

PRODUCT CODE: 18G: 01-014 ; 20G: 01-010

#### 1. Brief introduction

The Disposable needle used together with sterile syringes or infusion/transfusion sets for medicine infusion and blood collection, it assembled by hub, needle tube, protect cap, All materials used in this products can meet medical requirement; sterilized by ETO, it characterized with no-toxically pyrogen-free, easy to use, and with sharp needle. According to the needle tube size, it can specify to 30G, 29G, 28G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G and so on.

#### 2. Accessories and Components

Drawing of a representing product variant: detail see annex 1.

#### 3. Material requirement

All parts adopt high-polymer material harmless to human body, and technique requirement in accordance with ISO 7864:1993. Material for Disposable needle as follows: (table 1)

Components name	Material
Protection cap	PP (Ethylene-Polypropylene, Copolymer)
Needle tube	Stainless steel(SUS304)
Needle hub	PP (Ethylene-Polypropylene, Copolymer)
Lubricants	Silicone oil

#### 4. The design purpose and function of product

The Disposable needle used together with disposable syringe or disposable infusion/transfusion set for medicine infusion and blood collection. It can avoid inter-infection between patients.

To achieve above function, the product should have these functions: puncture, connection, transfusion.

##### 4.1 Puncture

Disposable needle tube is make of stainless steel for the puncture of skin, muscle, and vein to allow the transfusion and infusion of the medicine and blood, the collecting of the blood as well.

##### 4.2 Connection

One end of the Disposable needle is 6% luer slip connector or luer lock connector to connect with syringe or infusion/transfusion set.

##### 4.3 Transfusion

The needle tube and hub constitute a path for medicine to allow the medicine or the blood flow in it.

#### 5. The mostly technique parameter of product

##### 5.1 Physical requirement

##### 5.1.1 Fastness of connection

The needle tube of the Disposable needle and hub should connect tightly, and without separation when under as much pull force as bellow:

Loading force test of Disposable needle

Outer diameter of the needle tube	Loading force N
0.3 – 0.5	22
0.55 – 0.6	34
0.7	40
0.8	44
0.9	54
1.1 – 1.2	69

#### 5.1.2 Measure

Outer diameter of needle tube in accordance with ISO9626

Length of the needle tube in accordance with ISO7864:1993

#### 5.1.3 Hub of the Disposable needle

The hub of disposable conform to ISO7864:1993

#### 5.1.4 Needle tube

Needle tube conform to ISO9626:1991 and ISO7864:1993

#### 5.1.5 Appearance

The appearance conform to ISO7864:1993

#### 5.1.6 Needle hole should unblocked

Needle hole should conform to ISO7864:1993

#### 5.2 Chemical requirement

##### 5.2.1 Extractable metal content

When test in the method of color compare, the total volume of barium\chrome, copper, lead, stanium are not more than 5µg/mL, the volume of the cadmium less than 0.1µg/mL.

##### 5.2.2 PH degree

The margin of the PH degree between testing liquid and blank comparison liquid less than 1

#### 5.3 Biological requirement

Sterilized, non pyrogens, the index of the biological compatibility conform to ISO-10993.

#### 6. Packaging

The Disposable needle is supplied sterile in individual form-fill-seal package, inner a box and corrugated shipping carton.

#### 7. Function & Caution

Please pay attention to following instructions when you use it, As a disposable medical instruments:

- Don't use if package is open or damaged;
- For single use only discard after use;
- Use it within the valid date;
- Use it immediately when individual package opened.
- Unwell to used for a blood transfusion or have the blood composition.

#### 8. Classification according to Annex IX of Council Directive 93/42/EEC (Amending section in accordance with 2007/47/EC)

The Disposable needle is invasive device. It is intended for short-term use. According to rule 6 of annex IX of Council Directive 93/42/EEC (Amending section in accordance with 2007/47/EC), the Disposable needle belongs to class IIa medical device,

#### 9. UMDNS-Code: 12745

#### 10. Procedure of Certification

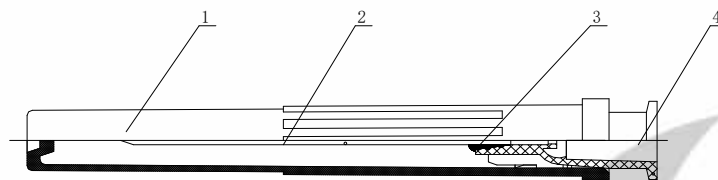
EC Directive 93/42/EEC (MDD 93/42/EEC as amended by directive 2007/47/EC) Annex II .3

#### 11. Sterilization

Sterilized with ETO.

#### ANNEX 1

Drawing of a representing product:



1 Protective cap; 2 Needle tube; 3 Adhesives, 4 Needle hub

Note: 1--- Disposable needle

#### Note:

Sterile, non-pyrogenic, Shelf life:5 year, ISO 13485 2003, CE 0197

**Product variant:**

Size ml	Needle Length	Blister Dimensions/ printing area	Inner Box Dimensions	Quantity, inner box	Export carton Dimensions/ Gross/net weight	Quant. Export carton	Article no MK 91.01.010 --	Article no
30G	1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6 KG/4KG	5000	91.01.010-900758	900758
29G	1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.4KG/4.4KG	5000	91.01.010-900741	900741
27G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.6KG/5.6KG	5000	91.01.010-904404	904404
27G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.7KG/5.7KG	5000	91.01.010-900734	900734
27G	4/5"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.7KG/4.7KG	5000	91.01.010-900727	900727
27G	3/4"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.7KG/4.9KG	5000	091.01.010-900710	900710
27G	1/2" 13mm	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.5KG/4.5KG	5000	91.01.010-870426	870426
27G	1/2" 12mm	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.5KG/4.5KG	5000	91.01.010-900703	900703
26G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.8KG/4.8KG	5000	91.01.010-900697	900697
26G	7/8"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.8KG/4.8KG	5000	91.01.010-900680	900680
26G	5/8"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.6KG/4.6KG	5000	91.01.010-900673	900673
26G	1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.1KG/4.1KG	5000	91.01.010-900383	900383
26G	3/8"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.7KG/4.7KG	5000	91.01.010-900666	900666
25G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.7KG/5.7KG	5000	91.01.010-900659	900659
25G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.75KG/4.75KG	5000	91.01.010-900642	900642
25G	3/4"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.8KG/4.8KG	5000	91.01.010-908006	908006
25G	5/8"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.8KG/4.8KG	5000	91.01.010-900345	900345
24G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.78KG/4.78KG	5000	91.01.010-900635	900635
23G	3 1/5"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8KG/6KG	5000	91.01.010-900628	900628
23G	2 2/5"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8KG/6KG	5000	91.01.010-900611	900611
23G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.9KG/5.9KG	5000	91.01.010-900604	900604
23G	1 1/4"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.4KG/5.4KG	5000	91.01.010-900291	900291
23G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.78KG/4.78KG	5000	91.01.010-900284	900284
22G	2"	85*19.21mm 75*15.21mm	105*84*86mm	100	545*240*450mm 9 KG/7KG	5000	91.01.010-900598	900598
22G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.9KG/5.9KG	5000	91.01.010-900260	900260
22G	1 1/4"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.4KG/5.4KG	5000	91.01.010-900581	900581
22G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	545*240*450mm 6.8KG/4.8KG	5000	91.01.010-900574	900574
22G	5/8"	85*19.21mm 75*15.21mm	105*84*86mm	100	545*240*450mm 9KG/8KG	5000	91.01.010-900567	900567
21G	4 4/5"	85*19.21mm 75*15.21mm	105*84*86mm	100	545*240*450mm 9KG/8KG	5000	91.01.010-900550	900550
21G	3 1/5"	85*19.21mm 75*15.21mm	105*84*86mm	100	545*240*450mm 9KG/8KG	5000	91.01.010-900543	900543
21G	2"	85*19.21mm 75*15.21mm	105*84*86mm	100	545*240*450mm 9.1KG/7.1KG	5000	91.01.010-900536	900536
21G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.9KG/5.9KG	5000	91.01.010-900192	900192
21G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	545*240*450mm 6.8KG/4.8KG	5000	91.01.010-900529	900529
21G	7/8"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.5KG/5.5KG	5000	91.01.010-900512	900512
21G	5/8"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7KG/5KG	5000	91.01.010-900505	900505
20G	2 3/4"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8KG/6KG	5000	91.01.010-900499	900499
20G	2"	85*19.21mm 75*15.21mm	105*84*86mm	100	545*240*450mm 9.2KG/7.2KG	5000	91.01.010-900485	900485
20G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.1KG/6.1KG	5000	91.01.010-900130	900130
20G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.2KG/6. KG	5000	91.01.010-900123	900123
19G	2"	85*19.21mm 75*15.21mm	105*84*86mm	100	545*240*450mm 9.2KG/7.2KG	5000	91.01.010-900475	900475
19G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	450*230*450mm 8.2KG/6.2KG	5000	91.01.010-900109	900109
19G	1 1/4"	85*19.21mm 75*15.21mm	105*84*86mm	100	450*230*450mm 8.2KG/6.2KG	5000	91.01.010-900468	900468
19G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.1KG/6.1KG	5000	91.01.010-900451	900451
18G	2"	85*19.21mm 75*15.21mm	105*84*86mm	100	545*240*450mm 9.5KG/7.5KG	5000	91.01.010-900444	900444
18G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.3KG/6.4KG	5000	91.01.010-900062	900062
16G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.4KG/6.3KG	5000	91.01.010-900437	900437
16G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.1KG/6.1KG	5000	91.01.010-900420	900420
15G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.4KG/6.3KG	5000	91.01.010-900413	900413
14G	3 1/4"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.8KG/6.8KG	5000	91.01.010-900406	900406
14G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.4KG/6.3KG	5000	91.01.010-900390	900390

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