



Technology File

File NO: KDL/Tech-33/01

Edition: D

General description of products -Sterile Irrigation Needles for Single Use

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<i>KDL</i>	General description of products- Sterile Irrigation Needles for Single Use	File No.	KDL/Tech-33/01	
		Version	D/0	Page 2of 7

Table of Contents

1. Regulatory Information

- 1.1 Manufacturer
- 1.2 Manufacturer Facility
- 1.3 OEM, critical suppliers, subcontractors
- 1.4 European Representative

2. Product and accessory classification, rule according to MDD, Annex IX and according to ISO 10993-1 Table 1 and 2

- 2.1 Conformity Assessment Route
- 2.2 UMDNS Code
- 2.3 Product History

3. Brief description of the product

- 3.1 Intended use
- 3.2 Configurations, variants
- 3.3 Applied standards

Annex 1: CE Certification

Annex 2: Sterile Irrigation Needles for Single Use variants:

KDL	General description of products- Sterile Irrigation Needles for Single Use	File No.	KDL/Tech-33/01	
		Version	D/0	Page 3of 7

1. Regulatory Information

1.1 Manufacturer:

Zhejiang kindly medical devices Co., Ltd.
No.252 Yongqiang Road.Yongzhou.Longwan.325024
Wenzhou. zhejiang P.R.C., China

1.2 Manufacturing Facility:

Zhejiang kindly medical devices Co., Ltd.
No.252 Yongqiang Road.Yongzhou.Longwan.325024
Wenzhou. zhejiang P.R.C., China

1.3 OEM, critical suppliers, subcontractors

Material and Components suppliers	OEM, critical suppliers, subcontractors
PP	Ningbo Jingyuan Trade Co.,Ltd.

1.4 European Representative

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80,20537 Hamburg Germany

2. Product and accessory classification, rule according to MDD, Annex IX and according to ISO 10993-1 Table 1 and 2:

The Sterile Irrigation Needles for Single Use is invasive device. It is intended for short-term use. According to rule 5 of Annex IX, of Council Directive 93/42/EEC (MDD 93/42/EEC as amended by directive 2007/47/EC), the Sterile Irrigation Needles for Single Use belongs to class II a medical device.

2.1 Conformity Assessment Route

Annex II .3

2.2 UMDNS Code:

20217

2.3 Product History: (e.g. FDA 510(k) or PMA clearance), market release, status of any pending request for market clearance; items sold)

The Sterile Irrigation Needles for Single Use has a long history of manufacturing and using all over the world. Kdl has been manufacturing, marketing and distributing Sterile Irrigation Needles for Single Use since 2001.01. Since it is relatively safe, reliable and simple to use, it is popularized in surgical treatment. Current market of Kdl Sterile Irrigation Needles for Single Use includes Europe, Middle East and South American.

Certificate: Detail see annex 1

Identification number: CE0123
(EC) Certificate (s): G1 13 01 36336 039
Expire date of the Certificate: 2014-12-27
Start of CE Marking: 2006
Place, Date of issue: Wenzhou 2013-03-22

3. Brief description of the product

The Sterile Irrigation needle for single use contains Protective cap, needle tube, needle hub, tubing. All parts and material for this product meet medical requirements, after sterilized by ETO, non-toxic, sterile, pyrogen free.

3.1 Intended use

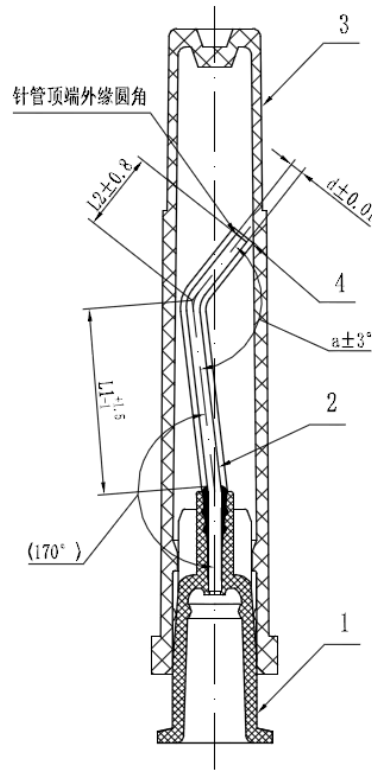
The Sterile Irrigation needle for single use intended to be used with syringe and infusion set(transfusion set) in cleaning process of dentistry and ophthalmology, Or used for preparation of liquid, it can avoid cross-infections among patients.

According to the needle tube size, it can specify to 27G、26G、25G、24G、23G、22G、21G、20G、19G、18G、17G、16G、15G、14G、13G and so on.

3.2 Configurations, variants

KDL	General description of products- Sterile Irrigation Needles for Single Use	File No.	KDL/Tech-33/01	
		Version	D/0	Page 4of 7

Drawing of a representing product variant
Drawing of a representing product:



1 Needle hub; 2 Needle tube; 3 Protective cap (or "have no use for"), 4 tubing

Note: 1--- Irrigation needle

Product variant 1 (吸塑包装):

Size ml	Needle Length	Blister Dimensions/ printing area	Inner Box Dimensions	Quantity inner box	Export carton Dimensions/ Gross/net weight	Quant. Export carton
27G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.6KG/5.6KG	5000
27G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.7KG/5.7KG	5000
27G	4/5"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.7KG/4.7KG	5000
27G	3/4"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.7KG/4.9KG	5000
27G	1/2" 13mm	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.5KG/4.5KG	5000
27G	1/2" 12mm	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.5KG/4.5KG	5000
26G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.8KG/4.8KG	5000
26G	7/8"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.8KG/4.8KG	5000
26G	5/8"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.6KG/4.6KG	5000
26G	1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.1KG/4.1KG	5000
26G	3/8"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.7KG/4.7KG	5000
25G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.7KG/5.7KG	5000
25G	1	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.75KG/4.75KG	5000
25G	3/4"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.8KG/4.8KG	5000

KDL	General description of products- Sterile Irrigation Needles for Single Use				File No.	KDL/Tech-33/01	
					Version	D/0	Page 5 of 7

25G	5/8"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.8KG/4.8KG	5000
24G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.78KG/4.78KG	5000
23G	3 1/5"					
23G	2 2/5"					
23G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.9KG/5.9KG	5000
23G	1 1/4"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.4KG/5.4KG	5000
23G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 6.78KG/4.78KG	5000
22G	2"	110*19.21mm 75*15.21mm	105*84*110m m	100	545*240*450mm 9.KG/7KG	5000
22G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.9KG/5.9KG	5000
22G	1 1/4"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.4KG/5.4KG	5000
22G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	545*240*450mm 6.8KG/4.8KG	5000
22G	5/8"	85*19.21mm 75*15.21mm	105*84*86mm	100	545*240*450mm 9KG/8KG	5000
21G	4 4/5"					
21G	3 1/5"					
21G	2"	110*19.21mm 75*15.21mm	105*84*110m m	100	545*240*450mm 9.1KG/7.1KG	5000
21G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.9KG/5.9KG	5000
21G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	545*240*450mm 6.8KG/4.8KG	5000
21G	7/8"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7.5KG/5.5KG	5000
21G	5/8"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 7KG/5KG	5000
20G	2 3/4"					
20G	2"	110*19.21mm 75*15.21mm	105*84*110m m	100	545*240*450mm 9.2KG/7.2KG	5000
20G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.1KG/6.1KG	5000
20G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.2KG/6.2KG	5000
19G	2"	110*19.21mm 75*15.21mm	105*84*110m m	100	545*240*450mm 9.2KG/7.2KG	5000
19G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	450*230*450mm 8.2KG/6.2KG	5000
19G	1 1/4"	85*19.21mm 75*15.21mm	105*84*86mm	100	450*230*450mm 8.2KG/6.2KG	5000
19G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.1KG/6.1KG	5000
18G	2"	110*19.21mm 75*15.21mm	105*84*110m m	100	545*240*450mm 9.5KG/7.5KG	5000
18G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.3KG/6.4KG	5000
16G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.4KG/6.3KG	5000
16G	1"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.1KG/6.1KG	5000
15G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.4KG/6.3KG	5000
14G	3 1/4"					
14G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.4KG/6.3KG	5000
13G	1 1/2"	85*19.21mm 75*15.21mm	105*84*86mm	100	460*230*450mm 8.8KG/6.8KG	5000

KDL	General description of products- Sterile Irrigation Needles for Single Use	File No.	KDL/Tech-33/01	
		Version	D/0	Page 6 of 7

Product variant 2 (纸塑袋,不同的针管长度与针管弯度, 会有不同包装尺寸, 以下仅一例子) :

Size ml	Blister Dimensions	Inner Box Dimensions	Quantity. inner box	Export carton Dimensions/	Quant. Export carton
27G-13G	160*65MM	185*95*120mm	100	505*390*510mm	4000

3.3 Applied standards

The standards applied in the design, manufacture, packaging and labeling of the Sterile Irrigation Needles for Single Use product lines are listed in the following table.

Regulations/ Standards	Description
YZB Zhe 0229-2011	Sterile Irrigation needles for single use
MEDDEV.2.7.1 Rev.3	Guidelines on medical devices
EN 556-1:2001/ AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 980:2008	Symbols for use in the labelling of medical devices
EN 1041:2008	Information Supplied by the Manufacturer with Medical Devices
EN 15986:2011	Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates
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
EN ISO 11737-2:2009	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11138-1:2006	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
EN ISO 11138-2:2009	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2006/AC:2009	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on product
EN ISO 13485:2003/AC2009	Medical Devices – Quality management system – Requirements for regulatory purposes
EN ISO 14155-1:2009	Clinical investigation of medical devices for human subjects - Part 1: General requirements
ISO 14698-1:2003	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
ISO 14644-1:2002	Cleanrooms and Associated Controlled Environments Part 1: Classification and Air Cleanliness
EN ISO 14971:2009	Medical Devices – Application of Risk Management to Medical Devices
EN ISO10993-1:2009	Biological evaluation of medical devices — Part 1 Evaluation and testing within a risk management process
EN ISO10993-4:2009	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
EN ISO10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2008/AC:2009	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals

<i>KDL</i>	General description of products- Sterile Irrigation Needles for Single Use	File No.	KDL/Tech-33/01	
		Version	D/0	Page 7 of 7

EN ISO10993-10:2010	Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity
EN ISO10993-11:2009	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

Annex 1

CE Certificate

Detail in annex 1