



EC Declaration of Conformity

Manufacture: Alton (Shanghai) Medical Instruments Co., Ltd

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Product Name: Disposable Grasping Forceps

Model Name: Suffix with GI, GJ, GK, GH, GM103, GM103-H, GM105, GM105-H, GM102, GL0, GL1, GL2, GL3, GL4, GL5, GL-1, GL-2, GW, and DC-2.

(See the attached list of disposable grasping forceps)

Model Numbers: 18

The typical models list is attached as followed:

The typical models list of disposable grasping forceps

No	Product Name	Model Name	Size
1	Disposable Grasping Forceps (Rat Tooth Type)	AF-D1810GI	Φ1.8×1000mm
		AF-D1812GI	Φ1.8×1200mm
		AF-D1815GI	Φ1.8×1500mm
		AF-D1816GI	Φ1.8×1600mm
		AF-D2416GI	Φ2.4×1600mm
		AF-D2418GI	Φ2.4×1800mm
		AF-D2421GI	Φ2.4×2100mm
		AF-D2423GI	Φ2.4×2300mm
2	Disposable Grasping Forceps (Rat Tooth With Alligator Type)	AF-D1810GJ	Φ1.8×1000mm
		AF-D1812GJ	Φ1.8×1200mm
		AF-D1815GJ	Φ1.8×1500mm
		AF-D1816GJ	Φ1.8×1600mm
		AF-D2416GJ	Φ2.4×1600mm

		AF-D2418GJ	Φ2.4×1800mm
		AF-D2421GJ	Φ2.4×2100mm
		AF-D2423GJ	Φ2.4×2300mm
3	Disposable Grasping Forceps (Pelican Type)	AF-D1810GK	Φ1.8×1000mm
		AF-D1812GK	Φ1.8×1200mm
		AF-D1815GK	Φ1.8×1500mm
		AF-D1816GK	Φ1.8×1600mm
		AF-D2416GK	Φ2.4×1600mm
		AF-D2418GK	Φ2.4×1800mm
		AF-D2421GK	Φ2.4×2100mm
		AF-D2423GK	Φ2.4×2300mm
4	Disposable Grasping Forceps (Alligator Type)	AF-D1810GH	Φ1.8×1000mm
		AF-D1812GH	Φ1.8×1200mm
		AF-D1815GH	Φ1.8×1200mm
		AF-D1816GH	Φ1.8×1600mm
		AF-D2416GH	Φ2.4×1600mm
		AF-D2418GH	Φ2.4×1800mm
		AF-D2421GH	Φ2.4×2100mm
		AF-D2423GH	Φ2.4×2300mm
5	Disposable Grasping Forceps (3-Prong Type)	AF-D1807GM103	Φ1.8×700mm
		AF-D1810GM103	Φ1.8×1000mm
		AF-D1812GM103	Φ1.8×1200mm
		AF-D1815GM103	Φ1.8×1500mm
		AF-D1825GM103	Φ1.8×2500mm
		AF-D2416GM103	Φ2.4×1600mm
		AF-D2417GM103	Φ2.4×1700mm
		AF-D2418GM103	Φ2.4×1800mm
		AF-D2421GM103	Φ2.4×2100mm
		AF-D2423GM103	Φ2.4×2300mm
6	Disposable Grasping Forceps (3-Prong Hook Type)	AF-D1807GM103-H	Φ1.8×700mm
		AF-D1810GM103-H	Φ1.8×1000mm
		AF-D1812GM103-H	Φ1.8×1200mm
		AF-D1815GM103-H	Φ1.8×1500mm
		AF-D1825GM103-H	Φ1.8×2500mm
		AF-D2416GM103-H	Φ2.4×1600mm
		AF-D2417GM103-H	Φ2.4×1700mm
		AF-D2418GM103-H	Φ2.4×1800mm
		AF-D2421GM103-H	Φ2.4×2100mm
		AF-D2423GM103-H	Φ2.4×2300mm
7	Disposable Grasping Forceps (5-Prong Type)	AF-D1807GM105	Φ1.8×700mm
		AF-D1810GM105	Φ1.8×1000mm
		AF-D1812GM105	Φ1.8×1200mm
		AF-D1815GM105	Φ1.8×1500mm

		AF-D1825GM105	Φ1.8×2500mm
		AF-D2416GM105	Φ2.4×1600mm
		AF-D2417GM105	Φ2.4×1700mm
		AF-D2418GM105	Φ2.4×1800mm
		AF-D2421GM105	Φ2.4×2100mm
		AF-D2423GM105	Φ2.4×2300mm
8	Disposable Grasping Forceps (5-Prong Hook Type)	AF-D1807GM105-H	Φ1.8×700mm
		AF-D1810GM105-H	Φ1.8×1000mm
		AF-D1812GM105-H	Φ1.8×1200mm
		AF-D1815GM105-H	Φ1.8×1500mm
		AF-D1825GM105-H	Φ1.8×2500mm
		AF-D2416GM105-H	Φ2.4×1600mm
		AF-D2417GM105-H	Φ2.4×1700mm
		AF-D2418GM105-H	Φ2.4×1800mm
		AF-D2421GM105-H	Φ2.4×2100mm
		AF-D2423GM105-H	Φ2.4×2300mm
9	Disposable Grasping Forceps (2-Prong Type)	AF-D1807GM102	Φ1.8×700mm
		AF-D1810GM102	Φ1.8×1000mm
		AF-D1812GM102	Φ1.8×1200mm
		AF-D1815GM102	Φ1.8×1500mm
		AF-D2416GM102	Φ2.4×1600mm
		AF-D2417GM102	Φ2.4×1700mm
		AF-D2418GM102	Φ2.4×1800mm
		AF-D2421GM102	Φ2.4×2100mm
		AF-D2423GM102	Φ2.4×2300mm
10	Disposable Grasping Forceps (Fold Angular Basket Type, Stainless Steel)	AF-D1807GL0	Φ1.8×700mm
		AF-D1810GL0	Φ1.8×1000mm
		AF-D1812GL0	Φ1.8×1200mm
		AF-D1815GL0	Φ1.8×1500mm
		AF-D1816GL0	Φ1.8×1600mm
		AF-D1825GL0	Φ1.8×2500mm
		AF-D2415GL0	Φ2.4×1500mm
		AF-D2417GL0	Φ2.4×1700mm
		AF-D2418GL0	Φ2.4×1800mm
		AF-D2421GL0	Φ2.4×2100mm
		AF-D2423GL0	Φ2.4×2300mm
11	Disposable Grasping Forceps (Basket Without Tip Type, Nitinol)	AF-D1007GL1	Φ1.0×700mm
		AF-D1010GL1	Φ1.0×1000mm
		AF-D1012GL1	Φ1.0×1200mm
		AF-D1807GL1	Φ1.8×700mm
		AF-D1810GL1	Φ1.8×1000mm
		AF-D1812GL1	Φ1.8×1200mm
		AF-D1815GL1	Φ1.8×1500mm

		AF-D1816GL1	Φ1.8×1600mm
		AF-D1825GL1	Φ1.8×2500mm
		AF-D2415GL1	Φ2.4×1500mm
		AF-D2417GL1	Φ2.4×1700mm
		AF-D2418GL1	Φ2.4×1800mm
		AF-D2421GL1	Φ2.4×2100mm
		AF-D2423GL1	Φ2.4×2300mm
12	Disposable Grasping Forceps (Spirality Basket Type, Nitinol)	AF-D1007GL2	Φ1.0×700mm
		AF-D1010GL2	Φ1.0×1000mm
		AF-D1012GL2	Φ1.0×1200mm
		AF-D1807GL2	Φ1.8×700mm
		AF-D1810GL2	Φ1.8×1000mm
		AF-D1812GL2	Φ1.8×1200mm
		AF-D1815GL2	Φ1.8×1500mm
		AF-D1816GL2	Φ1.8×1600mm
		AF-D1825GL2	Φ1.8×2500mm
		AF-D2415GL2	Φ2.4×1500mm
		AF-D2417GL2	Φ2.4×1700mm
		AF-D2418GL2	Φ2.4×1800mm
		AF-D2421GL2	Φ2.4×2100mm
AF-D2423GL2	Φ2.4×2300mm		
13	Disposable Grasping Forceps (Spirality Basket Type, Stainless Steel)	AF-D1007GL3	Φ1.0×700mm
		AF-D1010GL3	Φ1.0×1000mm
		AF-D1012GL3	Φ1.0×1200mm
		AF-D1807GL3	Φ1.8×700mm
		AF-D1810GL3	Φ1.8×1000mm
		AF-D1812GL3	Φ1.8×1200mm
		AF-D1815GL3	Φ1.8×1500mm
		AF-D1816GL3	Φ1.8×1600mm
		AF-D1825GL3	Φ1.8×2500mm
		AF-D2415GL3	Φ2.4×1500mm
		AF-D2417GL3	Φ2.4×1700mm
		AF-D2418GL3	Φ2.4×1800mm
		AF-D2421GL3	Φ2.4×2100mm
AF-D2423GL3	Φ2.4×2300mm		
14	Disposable Grasping Forceps (Basket With Tip Type, Nitinol)	AF-D1007GL4	Φ1.0×700mm
		AF-D1010GL4	Φ1.0×1000mm
		AF-D1012GL4	Φ1.0×1200mm
15	Disposable Grasping Forceps (Basket With Tip Type, Stainless Steel)	AF-D1007GL5	Φ1.0×700mm
		AF-D1010GL5	Φ1.0×1000mm
		AF-D1012GL5	Φ1.0×1200mm
16	Disposable Grasping Forceps (ERCP Basket Type)	AF-D2419GL-1	Φ2.4×1900mm, single lumen
		AF-D2421GL-1	Φ2.4×1900mm, single lumen

		AF-D2419GL-2	Φ2.4×2100mm, double lumen
		AF-D2421GL-2	Φ2.4×2100mm, double lumen
17	Disposable Grasping Forceps (Snare with bag Type)	AF-D1810GW	Φ1.8×1000mm
		AF-D1812GW	Φ1.8×1200mm
		AF-D1815GW	Φ1.8×1500mm
		AF-D1816GW	Φ1.8×1600mm
		AF-D2415GW	Φ2.4×1500mm
		AF-D2417GW	Φ2.4×1700mm
		AF-D2418GW	Φ2.4×1800mm
		AF-D2421GW	Φ2.4×2100mm
		AF-D2423GW	Φ2.4×2300mm
18	Disposable Grasping Forceps (Cold Snare Type, without clip for electrode connection)	AF-D1810DC-2	Φ1.8×1000mm
		AF-D1812DC-2	Φ1.8×1200mm
		AF-D1815DC-2	Φ1.8×1500mm
		AF-D1816DC-2	Φ1.8×1600mm
		AF-D1825DC-2	Φ1.8×2500mm
		AF-D2416DC-2	Φ2.4×1600mm
		AF-D2418DC-2	Φ2.4×1800mm
		AF-D2421DC-2	Φ2.4×2100mm
		AF-D2423DC-2	Φ2.4×2300mm

UMDNS Code: 15-628 (MD: 0106)

Classification (MDD, Annex IX): IIa, rule 6

Conformity Assessment Route: Annex V

We herewith declare that above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

Identification number: CE0123

(EC) Certificate: G2 17 12 57249 008

Report No.: SH1742702

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Haoxiang He - General Manager -

Signature:

Position: General Manager