Dokument podpisany przez ŁUKASZ ROMAN KRUCK
Data: 2024.06.04 07:33:06 CEST

Declaration of Conformity

Manufacturer: Transmed (China) CO., Ltd.

Address: Room 406, Building 3, Phase 2 Accelerator, No.11 Yaogu Avenue, Jiangbei New Area, 210032, Nanjing, Jiangsu Province, P.R.China

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

Product Name: Sterile Repositionable Hemostasis Clipping Device

Model Code: Please see attachment 2

UMDNS code: 10904

Classification: Clip Assembly: Class IIa (Annex IX, Rule 7 of MDD 93/42/EEC)
Delivery System: Class IIa (Annex IX, Rule 5 of MDD93/42/EEC)

Conformity Assessment Route: Annex V of MDD 93/42/EEC

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

DIRECTIVES

General applicable directives:

Medical Device Directive: Council Directive 93/42/EEC concerning medical devices

Standard:

All applicable harmonized standards published in the Official Journal of the European Communities.

- ✧ EN ISO13485:2016 Medical devices – Quality management systems-Requirements for regulatory purposes
- ✧ EN ISO14971:2019 Medical devices - Application of risk management to medical devices

✧ EN1041:2008+A1:2013 Information supplied by the manufacturer with medical devices

The detail harmonized standards see Attachment 1

Notified Body:	SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium
Identification number:	CE1639
Certificate Number:	CN19/41070
Expire date of the certificate:	24 May 2024
Place, Date of Certificate:	Nanjing, 2016.02.16

Signature: Teresa Fang **Date:** 2021-06-30

Name：Fang Ling (Teresa Fang)

Position：Management Representative

✧ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

✧ EN ISO13485:2016 Medical devices – Quality management systems-Requirements for regulatory purposes

✧ EN ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements?

✧ EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

✧ ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

✧ EN ISO 10993-3:2014 Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

✧ EN ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

✧ EN ISO 10993-6:2016 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation

✧ EN ISO 10993-7:2008+AC:2009 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals

✧ EN ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity

✧ EN ISO 10993-11:2009 Biological evaluation of medical devices -- Part 11: Tests for Systemic Toxicity

✧ EN ISO 11135:2014+AMD1 2019 Sterilization of health care products —Ethylene oxide —Requirements for development, validation and routine control of a sterilization process for medical devices

✧ EN ISO 11607-1:2020: Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems

✧ EN ISO 11607-2:2020: Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes

✧ ISTA-2A:2011: Series Partial Simulation Performance Test Procedure (Packaged-Products 150lb (68kg) or less)

✧ ASTM F1140/F1140M-13, Standard Test Methods For Internal Pressurization Failure Resistance Of Unrestrained Packages.

✧ ASTM F1886/F1886M: 2016 Standard Test Method for Determining Integrity of

Seals for Flexible Packaging by Visual Inspection

✧ EN1041:2008+A1: 2013 Information supplied by the manufacturer with medical devices

✧ SG5/N2R8:2007 Clinical Evaluation

✧ EN ISO 14644-1:2015 Cleanroom and associated controlled environments - Part 1: Classification of air cleanliness

✧ EN ISO 11737-1:2018 Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products

✧ 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

✧ ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

✧ EN 62366-1:2015 Medical devices – Application of usability engineering to medical devices

✧ MEDDEV 2.7.1 (Rev. 4, 2016) Clinical evaluation: a guide for manufacturers and notified bodies

✧ MEDDEV 2.12.1 (Rev. 8, 2013) Guidelines on a medical devices vigilance system

✧ MEDDEV 2.12.2 (Rev. 2, 2012) Post market clinical follow-up studies a guide for manufacturers and notified bodies

✧ EN ISO 14698-1:2014 Cleanrooms and associated controlled environments - Biocontamination control -Part 1 :General principles and methods

✧ ISO 8600-1: 2015 Optics and photonics —Medical endoscopes and endotherapy devices —Part 1: General requirements

Attachment 2

Sterile Repositionable Hemostasis Clipping Device

Unit：mm

NO	REF (Transmed)	Open width	Maximal Outer Diameter of the Insertion Part	work length	coating	Working Channel
Normal type						
1	A01001	8+2/0	1.8±0.15	1550±50	uncoated	≥2.8
2	A01002	8+2/0	1.8±0.15	1650±50	uncoated	≥2.8
3	A01003	8+2/0	1.8±0.15	1950±50	uncoated	≥2.8
4	A01004	8+2/0	1.8±0.15	2300±50	uncoated	≥2.8
5	A01005	8+2/0	1.8±0.15	2350±50	uncoated	≥2.8
6	A01006	8+2/0	1.8±0.15	2700±50	uncoated	≥2.8
7	A01007	8+2/0	2.3±0.15	1550±50	uncoated	≥2.8
8	A01008	8+2/0	2.3±0.15	1650±50	uncoated	≥2.8
9	A01009	8+2/0	2.3±0.15	1950±50	uncoated	≥2.8
10	A01010	8+2/0	2.3±0.15	2300±50	uncoated	≥2.8
11	A01011	8+2/0	2.3±0.15	2350±50	uncoated	≥2.8
12	A01012	8+2/0	2.3±0.15	2700±50	uncoated	≥2.8
13	A01013	8+2/0	2.6±0.15	1550±50	uncoated	≥2.8
14	A01014	8+2/0	2.6±0.15	1650±50	uncoated	≥2.8
15	A01015	8+2/0	2.6±0.15	1950±50	uncoated	≥2.8
16	A01016	8+2/0	2.6±0.15	2300±50	uncoated	≥2.8
17	A01017	8+2/0	2.6±0.15	2350±50	uncoated	≥2.8

NO	REF（Transmed）	Open width	Maximal Outer Diameter of the Insertion Part	work length	coating	Working Channel
18	A01018	8+2/0	2.6±0.15	2700±50	uncoated	⩾2.8
19	A01019	11±1	1.8±0.15	1550±50	uncoated	⩾2.8
20	A01020	11±1	1.8±0.15	1650±50	uncoated	⩾2.8
21	A01021	11±1	1.8±0.15	1950±50	uncoated	⩾2.8
22	A01022	11±1	1.8±0.15	2300±50	uncoated	⩾2.8
23	A01023	11±1	1.8±0.15	2350±50	uncoated	⩾2.8
24	A01024	11±1	1.8±0.15	2700±50	uncoated	⩾2.8
25	A01025	11±1	2.3±0.15	1550±50	uncoated	⩾2.8
26	A01026	11±1	2.3±0.15	1650±50	uncoated	⩾2.8
27	A01027	11±1	2.3±0.15	1950±50	uncoated	⩾2.8
28	A01028	11±1	2.3±0.15	2300±50	uncoated	⩾2.8
29	A01029	11±1	2.3±0.15	2350±50	uncoated	⩾2.8
30	A01030	11±1	2.3±0.15	2700±50	uncoated	⩾2.8
31	A01031	11±1	2.6±0.15	1550±50	uncoated	⩾2.8
32	A01032	11±1	2.6±0.15	1650±50	uncoated	⩾2.8
33	A01033	11±1	2.6±0.15	1950±50	uncoated	⩾2.8
34	A01034	11±1	2.6±0.15	2300±50	uncoated	⩾2.8
35	A01035	11±1	2.6±0.15	2350±50	uncoated	⩾2.8
36	A01036	11±1	2.6±0.15	2700±50	uncoated	⩾2.8
37	A01037	16±2	1.8±0.15	1550±50	uncoated	⩾2.8

NO	REF（Transmed）	Open width	Maximal Outer Diameter of the Insertion Part	work length	coating	Working Channel
38	A01038	16±2	1.8±0.15	1650±50	uncoated	⩾2.8
39	A01039	16±2	1.8±0.15	1950±50	uncoated	⩾2.8
40	A01040	16±2	1.8±0.15	2300±50	uncoated	⩾2.8
41	A01041	16±2	1.8±0.15	2350±50	uncoated	⩾2.8
42	A01042	16±2	1.8±0.15	2700±50	uncoated	⩾2.8
43	A01043	16±2	2.3±0.15	1550±50	uncoated	⩾2.8
44	A01044	16±2	2.3±0.15	1650±50	uncoated	⩾2.8
45	A01045	16±2	2.3±0.15	1950±50	uncoated	⩾2.8
46	A01046	16±2	2.3±0.15	2300±50	uncoated	⩾2.8
47	A01047	16±2	2.3±0.15	2350±50	uncoated	⩾2.8
48	A01048	16±2	2.3±0.15	2700±50	uncoated	⩾2.8
49	A01049	16±2	2.6±0.15	1550±50	uncoated	⩾2.8
50	A01050	16±2	2.6±0.15	1650±50	uncoated	⩾2.8
51	A01051	16±2	2.6±0.15	1950±50	uncoated	⩾2.8
52	A01052	16±2	2.6±0.15	2300±50	uncoated	⩾2.8
53	A01053	16±2	2.6±0.15	2350±50	uncoated	⩾2.8
54	A01054	16±2	2.6±0.15	2700±50	uncoated	⩾2.8
High-end type						
55	A01055	8+2/0	1.8±0.15	1550±50	pink coated	⩾2.8
56	A01056	8+2/0	1.8±0.15	1650±50	pink coated	⩾2.8

NO	REF（Transmed）	Open width	Maximal Outer Diameter of the Insertion Part	work length	coating	Working Channel
57	A01057	8+2/0	1.8±0.15	1950±50	pink coated	⩾2.8
58	A01058	8+2/0	1.8±0.15	2300±50	pink coated	⩾2.8
59	A01059	8+2/0	1.8±0.15	2350±50	pink coated	⩾2.8
60	A01060	8+2/0	1.8±0.15	2700±50	pink coated	⩾2.8
61	A01061	8+2/0	2.3±0.15	1550±50	pink coated	⩾2.8
62	A01062	8+2/0	2.3±0.15	1650±50	pink coated	⩾2.8
63	A01063	8+2/0	2.3±0.15	1950±50	pink coated	⩾2.8
64	A01064	8+2/0	2.3±0.15	2300±50	pink coated	⩾2.8
65	A01065	8+2/0	2.3±0.15	2350±50	pink coated	⩾2.8
66	A01066	8+2/0	2.3±0.15	2700±50	pink coated	⩾2.8
67	A01067	8+2/0	2.6±0.15	1550±50	pink coated	⩾2.8
68	A01068	8+2/0	2.6±0.15	1650±50	pink coated	⩾2.8
69	A01069	8+2/0	2.6±0.15	1950±50	pink coated	⩾2.8
70	A01070	8+2/0	2.6±0.15	2300±50	pink coated	⩾2.8
71	A01071	8+2/0	2.6±0.15	2350±50	pink coated	⩾2.8
72	A01072	8+2/0	2.6±0.15	2700±50	pink coated	⩾2.8
73	A01073	11±1	1.8±0.15	1550±50	blue coated	⩾2.8
74	A01074	11±1	1.8±0.15	1650±50	blue coated	⩾2.8
75	A01075	11±1	1.8±0.15	1950±50	blue coated	⩾2.8
76	A01076	11±1	1.8±0.15	2300±50	blue coated	⩾2.8

NO	REF（Transmed）	Open width	Maximal Outer Diameter of the Insertion Part	work length	coating	Working Channel
77	A01077	11±1	1.8±0.15	2350±50	blue coated	⩾2.8
78	A01078	11±1	1.8±0.15	2700±50	blue coated	⩾2.8
79	A01079	11±1	2.3±0.15	1550±50	blue coated	⩾2.8
80	A01080	11±1	2.3±0.15	1650±50	blue coated	⩾2.8
81	A01081	11±1	2.3±0.15	1950±50	blue coated	⩾2.8
82	A01082	11±1	2.3±0.15	2300±50	blue coated	⩾2.8
83	A01083	11±1	2.3±0.15	2350±50	blue coated	⩾2.8
84	A01084	11±1	2.3±0.15	2700±50	blue coated	⩾2.8
85	A01085	11±1	2.6±0.15	1550±50	blue coated	⩾2.8
86	A01086	11±1	2.6±0.15	1650±50	green coated	⩾2.8
87	A01087	11±1	2.6±0.15	1950±50	green coated	⩾2.8
88	A01088	11±1	2.6±0.15	2300±50	green coated	⩾2.8
89	A01089	11±1	2.6±0.15	2350±50	green coated	⩾2.8
90	A01090	11±1	2.6±0.15	2700±50	blue coated	⩾2.8
91	A01091	16±2	1.8±0.15	1550±50	yellow coated	⩾2.8
92	A01092	16±2	1.8±0.15	1650±50	yellow coated	⩾2.8
93	A01093	16±2	1.8±0.15	1950±50	yellow coated	⩾2.8
94	A01094	16±2	1.8±0.15	2300±50	yellow coated	⩾2.8
95	A01095	16±2	1.8±0.15	2350±50	yellow coated	⩾2.8
96	A01096	16±2	1.8±0.15	2700±50	yellow coated	⩾2.8

NO	REF（Transmed）	Open width	Maximal Outer Diameter of the Insertion Part	work length	coating	Working Channel
97	A01097	16±2	2.3±0.15	1550±50	yellow coated	⩾2.8
98	A01098	16±2	2.3±0.15	1650±50	yellow coated	⩾2.8
99	A01099	16±2	2.3±0.15	1950±50	yellow coated	⩾2.8
100	A01100	16±2	2.3±0.15	2300±50	yellow coated	⩾2.8
101	A01101	16±2	2.3±0.15	2350±50	yellow coated	⩾2.8
102	A01102	16±2	2.3±0.15	2700±50	yellow coated	⩾2.8
103	A01103	16±2	2.6±0.15	1550±50	yellow coated	⩾2.8
104	A01104	16±2	2.6±0.15	1650±50	green coated	⩾2.8
105	A01105	16±2	2.6±0.15	1950±50	green coated	⩾2.8
106	A01106	16±2	2.6±0.15	2300±50	green coated	⩾2.8
107	A01107	16±2	2.6±0.15	2350±50	green coated	⩾2.8
108	A01108	16±2	2.6±0.15	2700±50	yellow coated	⩾2.8
109	DC0165	11±1	2.6±0.15	1650±50	blue coated	⩾2.8
110	DC0235	11±1	2.6±0.15	2350±50	blue coated	⩾2.8