Declaration of Conformity

Manufacturer:
Name: Suzhou Frankenman Medical Equipment Co., Ltd.
Address: 108 South Jinfeng Road, Suzhou High-New District, 215163 Suzhou, PEOPLE'S REPUBLIC OF CHINA
Tel: + 86-512-6878 0588/6878 0388
Fax: +86-512-6808 0025

European Representative:
Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175
Fax: 0049-40-255726

Product Name:
Single Use Transverse Cutting Linear Stapler and Reloads
Product code: See attachment A.
Product Classification: IIb
Rule of classification: Rule 8
GMDN Code: P45183
MD Code: MD 0302
Approach of product conformity verification: Annex II. Excluding (4)

We herewith declare that the above-mentioned products meet the provisions of the following EC MDD 93/42/EEC Council Directives and Standards. Suzhou Frankenman Medical Equipment Co., Ltd. is exclusively responsible for the DOC.

DIRECTIVES

General applicable directives:
Medical Device Directive: Council Directive MDD 93/42/EEC.
Standard:
All applicable harmonized Standards. See attachment B.

Notified Body: TüV SüD Product Service GmbH, Ridlerstraβe. 65, 80339 München, Germany
Identification Number: 0123
Certificate No: G1 091657 0014 Rev.02
Date of CE mark was affixed: May 9th, 2011
Expiration date of CE certificate: May 26th, 2024

Signature of issuing person:

FRANKENMAN MEDICAL EQUIPMENT CO., LTD. SUZHOU 320502191361 苏州法兰克曼医疗器械有限公司

Position: Management representative
Date: 2021.5.17
Issue Place: Suzhou

Schedule A of Declaration of conformity

Product Name/ Models:

Product	Single Use Transverse Cutting Linear Stapler and Reloads
Models	Stapler: HJG-H30W, HJG-H30B, HJG-H30G, HJG 40B, HJG 40Z, HJG 40H, HJG 60Z, HJG 60H, TCLS30W, TCLS30B, TCLS30G, TCLS40W, TCLS40B, TCLS40G, TCLS60B, TCLS60G Reloads: HJGZ-H30W, HJGZ-H30B, HJGZ-H30G, HJGZ 40B, HJGZ 40Z, HJGZ 40H, HJGZ 60Z, HJGZ 60H, TCLSR30W, TCLSR30B, TCLSR30G, TCLSR40W, TCLSR40B, TCLSR40G, TCLSR60B, TCLSR60G

Attachment B of Declaration of conformity

Standards List

No.	Document Number	Version	Name of document
1	EN ISO 13485 (ISO 13485)	2016 (2016)	Medical devices. Quality management systems. Requirements for regulatory purposes
2	MDD 93/42/EEC	2007	Medical Device Safety Directive
3	EN ISO 14971 (ISO 14971)	2019 (2019)	Medical devices -- Application of risk management to medical devices
4	EN ISO 10993-1 (ISO 10993-1)	2009 (2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5	EN ISO 10993-5 (ISO 10993-5)	2009 (2009)	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
6	EN ISO 10993-10 (ISO 10993-10)	2013 (2010)	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
7	EN ISO 10993-11 (ISO 10993-11)	2018 (2017)	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
8	EN ISO 15223-1 (ISO 15223-1)	2016 (2016)	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
9	ISO 15223-2	2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
10	EN 1041	2008	Information supplied by the manufacturer of medical devices
11	EN ISO 14155 (ISO 14155)	2011 (2011)	Clinical investigation of medical devices for human subjects -- Good clinical practice
12	MEDDEV 2.7/1	Revision 4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
13	EN ISO 11607-1 (ISO 11607-1)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 1:Requirements for materials,sterile barrier systems and packaging systems
14	EN ISO 11607-2 (ISO 11607-2)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 2:Validation requirements for forming,sealing and assembly processes
15	EN ISO 11137-1 (ISO 11137-1)	2015 (2006)	Sterilization Of Health Care Products-Radiation-Part 1:Requirements For Development,Validation And Routine Control Of A Sterilization Process For Medical Devices
16	EN ISO 11137-2 (ISO 11137-2)	2015 (2013)	Sterilization Of Health Care Products-Radiation-Part 2:Establishing The Sterilization Dose

17	EN ISO 11737-1 (ISO 11737-1)	2018 (2018)	Sterilization of health care products. Microbiological methods. Part 1:Determination of a population of microorganisms on products
18	EN ISO 11737-2 (ISO 11737-2)	2009 (2019)	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
19	EN ISO 14644-1 (ISO 14644-1)	2015 (2015)	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
20	EN ISO 14644-2 (ISO 14644-2)	2015 (2015)	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
21	EN ISO 5832-2 (ISO 5832-2)	2018 (2018)	Implants for surgery. Metallic materials. Part 2:Unalloyed titanium
22	EN ISO 14630 (ISO 14630)	2012 (2012)	Non-active surgical implants -- General requirements
23	EN ISO 6507-1 (ISO 6507-1)	2018 (2018)	Metallic materials — Vickers hardness test — Part 1: Test method
24	ASTM D4169	2016	Standard Practice for Performance Testing of Shipping Containers and Systems
25	IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices

Declaration of Conformity

Manufacturer:
Name: Suzhou Frankenman Medical Equipment Co., Ltd.
Address: 108 South Jinfeng Road, Suzhou High-New District, 215163 Suzhou, PEOPLE'S REPUBLIC OF CHINA
Tel: + 86-512-6878 0588/6878 0388
Fax: +86-512-6808 0025

European Representative:
Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175
Fax: 0049-40-255726

Product Name:
Single Use Suction and Irrigation System
Product code: See attachment A.
Product Classification: IIa
Rule of classification: Rule 7
UMDNS Code: 12306
MD Code: MD 0106
Approach of product conformity verification: Annex II. Excluding (4)

We herewith declare that the above-mentioned products meet the provisions of the following EC MDD 93/42/EEC Council Directives and Standards. Suzhou Frankenman Medical Equipment Co., Ltd. is exclusively responsible for the DOC.

DIRECTIVES

General applicable directives:
Medical Device Directive: Council Directive MDD 93/42/EEC.
Standard:
All applicable harmonized Standards. See attachment B.

Notified Body: TüV SüD Product Service GmbH, Ridlerstraβe. 65, 80339 München, Germany
Identification Number: 0123
Certificate No: G1 091657 0014 Rev.02
Date of CE mark was affixed: May 9th, 2011
Expiration date of CE certificate: May 26th, 2024

Signature of issuing person:

FRANKENMAN MEDICAL EQUIPMENT CO., LTD. SUZHOU 320502191361 苏州法兰克曼医疗器械有限公司

Position: Management representative
Date: 2021.5.17
Issue Place: Suzhou

Attachment A of Declaration of conformity

Product Name/ Models:

Product	Single Use Suction and Irrigation System
Models	SIS328, SIS332, SIS342, SIS528, SIS532, SIS542, SIS1028, SIS1032, SIS1042, SIS328T, SIS332T, SIS342T, SIS528T, SIS532T, SIS542T, SIS1028T, SIS1032T, SIS1042T, HJY0328, HJY0332, HJY0342, HJY0528, HJY0532, HJY0542, HJY1028, HJY1032, HJY1042, HJYZ0328, HJYZ0332, HJYZ0342, HJYZ0528, HJYZ0532, HJYZ0542, HJYZ1028, HJYZ1032, HJYZ1042

Attachment B of Declaration of conformity

Standards List

No.	Document Number	Version	Name of document
1	EN ISO 13485 (ISO 13485)	2016 (2016)	Medical devices - Quality management system – for Regulatory Requirements
2	MDD93/42/EEC	2007	Medical Device Safety Directive
3	EN ISO 14971 (ISO 14971)	2019 (2019)	Medical Device -- Application of Risk Management for Medical Device
4	EN ISO 10993-1 (ISO 10993-1)	2009 (2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5	EN ISO 10993-5 (ISO 10993-5)	2009 (2009)	Biological Evaluation of Medical Device-Part 5: Test for Cytotoxicity: in vitro methods
6	EN ISO 10993-7 (ISO 10993-7)	2008 (2008)	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
7	EN ISO 10993-10 (ISO 10993-10)	2013 (2010)	Biological Evaluation of Medical Device-Part 10: Test for Irritation and Sterilization
8	EN ISO 10993-11 (ISO 10993-11)	2018 (2017)	Biological evaluation of medical devices-Part 11: Tests for systemic toxicity
9	EN ISO 15223-1 (ISO 15223-1)	2016 (2016)	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
10	ISO15223-2	2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
11	EN1041	2008	Information supplied by the manufacturer of medical devices
12	MEDDEV 2.7/1	Revision 4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
13	EN ISO 14155 (ISO 14155)	2011 (2011)	Clinical investigation of medical devices for human subjects -- Good clinical practice
14	EN ISO 11607-1 (ISO 11607-1)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 1:Requirements for materials,sterile barrier systems and packaging systems
15	EN ISO 11607-2 (ISO 11607-2)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 2:Validation requirements for forming,sealing and assembly processes
16	EN ISO 11135 (ISO 11135)	2014 (2014)	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices

17	EN ISO 11737-1 (ISO 11737-1)	2018 (2018)	Sterilization of Medical Device-Microorganisms Method-Part 1 Determination of the Microorganisms on Products
18	EN ISO 11737-2 (ISO 11737-2)	2009 (2019)	Sterilization of Medical Device- Microorganisms Method-Part 2: Asepsis Test carried out during sterilization
19	EN ISO 14644-1 (ISO 14644-1)	2015 (2015)	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
20	EN ISO 14644-2 (ISO 14644-2)	2015 (2015)	Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
21	EN ISO 14630 (ISO 14630)	2012 (2012)	Inactive surgical implants-general requirements
22	ASTM D4169	2016	Standard Practice for Performance Testing of Shipping Containers and Systems
23	IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices

Declaration of Conformity

Manufacturer:
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Fax: +86-512-6808 0025

European Representative:
Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175
Fax: 0049-40-255726

Product Name:
Disposable Reloadable Linear Stapler and Reloads/
Single use Reloadable Linear Stapler and Reloads
Product code: See attachment A.
Product Classification: IIb
Rule of classification: Rule 8
GMDN Code: P46335
MD Code: MD 0302
Approach of product conformity verification: Annex II. Excluding (4)

We herewith declare that the above-mentioned products meet the provisions of the following EC MDD 93/42/EEC Council Directives and Standards. Suzhou Frankenman Medical Equipment Co., Ltd. is exclusively responsible for the DOC.

DIRECTIVES

General applicable directives:
Medical Device Directive: Council Directive MDD 93/42/EEC.
Standard:
All applicable harmonized Standards. See attachment B.

Notified Body: TüV SüD Product Service GmbH, Ridlerstraβe. 65, 80339 München, Germany
Identification Number: 0123
Certificate No: G1 091657 0014 Rev.02
Date of CE mark was affixed: May 9th, 2011
Expiration date of CE certificate: May 26th, 2024

Signature of issuing person:

Position: Management representative
Date: 2021.5.17
Issue Place: Suzhou

Attachment A of Declaration of conformity

Product Name/ Models:

Product	Disposable Reloadable Linear Stapler and Reloads/ Single use Reloadable Linear Stapler and Reloads
Models	Stapler: LS 30W(HJF30B) LS 30B(HJF30Z) LS 30Y(HJF30S) LS 30G(HJF30H) LS 45B(HJF45Z) LS 45Y(HJF45S) LS 45G(HJF45H) LS 60B(HJF60Z) LS 60Y(HJF60S) LS 60G(HJF60H) LS 90B(HJF90Z) LS 90Y(HJF90S) LS 90G(HJF90H) Reloads: LSR 30W(HJFZ30B) LSR 30B(HJFZ30Z) LSR 30Y(HJFZ30S) LSR 30G(HJFZ30H) LSR 45B(HJFZ45Z) LSR 45Y(HJFZ45S) LSR 45G(HJFZ45H) LSR 60B(HJFZ60Z) LSR 60Y(HJFZ60S) LSR 60G(HJFZ60H) LSR 90B(HJFZ90Z) LSR 90Y(HJFZ90S) LSR 90G(HJFZ90H)

Attachment B of Declaration of conformity

Standards List

No.	Document Number	Version	Name of document
1	EN ISO 13485 (ISO 13485)	2016 (2016)	Medical devices - Quality management system – for Regulatory Requirements
2	MDD93/42/EEC	2007	Medical Device Safety Directive
3	EN ISO 14971 (ISO 14971)	2019 (2019)	Medical devices -- Application of risk management to medical devices
4	EN ISO 10993-1 (ISO 10993-1)	2009 (2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5	EN ISO 10993-5 (ISO 10993-5)	2009 (2009)	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
6	EN ISO 10993-10 (ISO 10993-10)	2013 (2010)	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
7	EN ISO 10993-11 (ISO 10993-11)	2018 (2017)	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
8	EN ISO 15223-1 (ISO 15223-1)	2016 (2016)	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
9	ISO 15223-2	2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
10	EN 1041	2008	Information supplied by the manufacturer of medical devices
11	MEDDEV 2.7/1	Revision 4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
12	EN ISO 14155 (ISO 14155)	2011 (2011)	Clinical investigation of medical devices for human subjects -- Good clinical practice
13	EN ISO 11607-1 (ISO 11607-1)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 1:Requirements for materials,sterile barrier systems and packaging systems
14	EN ISO 11607-2 (ISO 11607-2)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 2:Validation requirements for forming,sealing and assembly processes
15	EN ISO 11137-1 (ISO 11137-1)	2015 (2006)	Sterilization Of Health Care Products-Radiation-Part 1:Requirements For Development,Validation And Routine Control Of A Sterilization Process For Medical Devices
16	EN ISO 11137-2	2015	Sterilization Of Health Care Products-Radiation-Part

	(ISO 11137-2)	(2013)	2:Establishing The Sterilization Dose
17	EN ISO 11737-1 (ISO 11737-1)	2018 (2018)	Sterilization of health care products. Microbiological methods. Part 1:Determination of a population of microorganisms on products
18	EN ISO 11737-2 (ISO 11737-2)	2009 (2019)	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
19	EN ISO 14644-1 (ISO 14644-1)	2015 (2015)	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
20	EN ISO 14644-2 (ISO 14644-2)	2015 (2015)	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
21	EN ISO 5832-2 (ISO 5832-2)	2018 (2018)	Implants for surgery. Metallic materials. Part 2:Unalloyed titanium
22	EN ISO 14630 (ISO 14630)	2012 (2012)	Non-active surgical implants -- General requirements
23	EN ISO 6507-1 (ISO 6507-1)	2018 (2018)	Metallic materials — Vickers hardness test — Part 1: Test method
24	ASTM D4169	2016	Standard Practice for Performance Testing of Shipping Containers and Systems
25	IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices

Declaration of Conformity

Manufacturer:
Name: Suzhou Frankenman Medical Equipment Co., Ltd.
Address: 108 South Jinfeng Road, Suzhou High-New District, 215163 Suzhou, PEOPLE'S REPUBLIC OF CHINA
Tel: + 86-512-6878 0588/6878 0388
Fax: +86-512-6808 0025

European Representative:
Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175
Fax: 0049-40-255726

Product Name:
Disposable Reloadable Linear Cutter Stapler and Reloads/
Single Use Reloadable Linear Cutter Stapler and Reloads

Product code: See attachment A.
Product Classification: IIb
Rule of classification: Rule 8
GMDN Code: P45183
MD Code: MD 0302
Approach of product conformity verification: Annex II. Excluding (4)

We herewith declare that the above-mentioned products meet the provisions of the following EC MDD 93/42/EEC Council Directives and Standards. Suzhou Frankenman Medical Equipment Co., Ltd. is exclusively responsible for the DOC.

DIRECTIVES

General applicable directives:
Medical Device Directive: Council Directive MDD 93/42/EEC.
Standard:
All applicable harmonized Standards. See attachment B.

Notified Body: TüV SüD Product Service GmbH, Ridlerstraβe. 65, 80339 München, Germany
Identification Number: 0123
Certificate No: G1 091657 0014 Rev.02
Date of CE mark was affixed: May 9th, 2011
Expiration date of CE certificate: May 26th, 2024

Signature of issuing person:

SUZHOU FRANKENMAN MEDICAL EQUIPMENT CO., LTD. 苏州法兰克曼医疗器械有限公司 3205902191361 4

Position: Management representative
Date: 2021.5.17
Issue Place: Suzhou

Schedule A of Declaration of conformity

Product Name/ Models:

Product	Disposable Reloadable Linear Cutter Stapler and Reloads/ Single Use Reloadable Linear Cutter Stapler and Reloads
Models	Stapler: LC 60W（HJQ60-BY） LC 60B（HJQ60-ZY） LC 60Y（HJQ60-SY） LC 60G（HJQ60-HY） LS4 60W（HJQ60-BW） LS4 60B（HJQ60-ZW） LS4 60Y（HJQ60-SW） LS4 60G（HJQ60-HW） LC 80B（HJQ80-ZY） LC 80Y（HJQ80-SY） LC 80G（HJQ80-HY） LS4 80B（HJQ80-ZW） LS4 80Y（HJQ80-SW） LS4 80G（HJQ80-HW） LC 100B（HJQ100-ZY） LC 100Y（HJQ100-SY） LC 100G（HJQ100-HY） LS4 100B（HJQ100-ZW） LS4 100Y（HJQ100-SW） LS4 100G（HJQ100-HW） LCB60BPack3R LCG60BPack3R LCB80BPack3R LCG80BPack3R LCB100BPack3R LCG100BPack3R Reloads: LCR 60W（HJQZ60-B） LCR 60B（HJQZ60-Z） LCR 60Y（HJQZ60-S） LCR 60G（HJQZ60-H） LCR 80B（HJQZ80-Z） LCR 80Y（HJQZ80-S） LCR 80G（HJQZ80-H） LCR 100B（HJQZ100-Z） LCR 100Y（HJQZ100-S） LCR 100G（HJQZ100-H） LCR 60W/B/Y/G HJQZ60B/Z/S/H LCR 80W/B/Y/G

	HJQZ80B/Z/S/H LCR 100W/B/Y/G HJQZ100B/Z/S/H

Attachment B of Declaration of conformity - Standards List

No.	Document Number	Version	Name of document
1	EN ISO 13485 (ISO 13485)	2016 (2016)	Medical devices. Quality management systems. Requirements for regulatory purposes
2	MDD 93/42/EEC	2007	Medical Device Safety Directive
3	EN ISO 14971 (ISO 14971)	2019 (2019)	Medical devices -- Application of risk management to medical devices
4	EN ISO 10993-1 (ISO 10993-1)	2009 (2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5	EN ISO 10993-5 (ISO 10993-5)	2009 (2009)	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
6	EN ISO 10993-10 (ISO 10993-10)	2013 (2010)	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
7	EN ISO 10993-11 (ISO 10993-11)	2018 (2017)	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
8	EN ISO 15223-1 (ISO 15223-1)	2016 (2016)	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
9	ISO 15223-2	2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
10	EN 1041	2008	Information supplied by the manufacturer of medical devices
11	MEDDEV 2.7/1	Revision 4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
12	EN ISO 14155 (ISO 14155)	2011 (2011)	Clinical investigation of medical devices for human subjects -- Good clinical practice
13	EN ISO 11607-1 (ISO 11607-1)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 1:Requirements for materials,sterile barrier systems and packaging systems
14	EN ISO 11607-2 (ISO 11607-2)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 2:Validation requirements for forming,sealing and assembly processes
15	EN ISO 11137-1 (ISO 11137-1)	2015 (2006)	Sterilization Of Health Care Products-Radiation-Part 1:Requirements For Development,Validation And Routine Control Of A Sterilization Process For Medical Devices
16	EN ISO 11137-2 (ISO 11137-2)	2015 (2013)	Sterilization Of Health Care Products-Radiation-Part 2:Establishing The Sterilization Dose

17	EN ISO 11737-1 (ISO 11737-1)	2018 (2018)	Sterilization of health care products. Microbiological methods. Part 1:Determination of a population of microorganisms on products
18	EN ISO 11737-2 (ISO 11737-2)	2009 (2019)	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
19	EN ISO 14644-1 (ISO 14644-1)	2015 (2015)	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
20	EN ISO 14644-2 (ISO 14644-2)	2015 (2015)	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
21	EN ISO 5832-2 (ISO 5832-2)	2018 (2018)	Implants for surgery. Metallic materials. Part 2:Unalloyed titanium
22	EN ISO 14630 (ISO 14630)	2012 (2012)	Non-active surgical implants -- General requirements
23	ASTM D4169	2016	Standard Practice for Performance Testing of Shipping Containers and Systems
24	IEC 62366-1	2015	Medical devices – Part 1: Application of usability engineering to medical devices

Declaration of Conformity

Manufacturer:
Name: Suzhou Frankenman Medical Equipment Co., Ltd.
Address: 108 South Jinfeng Road, Suzhou High-New District, 215163 Suzhou, PEOPLE'S REPUBLIC OF CHINA
Tel: + 86-512-6878 0588/6878 0388
Fax: +86-512-6808 0025

European Representative:
Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175
Fax: 0049-40-255726

Product Name:
Single Use Purse String Forceps
Product code: See attachment A.
Product Classification: IIa
Rule of classification: Rule 6
UMDNS Code: 16651
MD Code: MD 0106
Approach of product conformity verification: Annex II. Excluding (4)

We herewith declare that the above-mentioned products meet the provisions of the following EC MDD 93/42/EEC Council Directives and Standards. Suzhou Frankenman Medical Equipment Co., Ltd. is exclusively responsible for the DOC.

DIRECTIVES

General applicable directives:
Medical Device Directive: Council Directive MDD 93/42/EEC.
Standard:
All applicable harmonized Standards. See attachment B.

Notified Body: TüV SüD Product Service GmbH, Ridlerstraβe. 65, 80339 München, Germany
Identification Number: 0123
Certificate No: G1 091657 0014 Rev.02
Date of CE mark was affixed: May 9th, 2011
Expiration date of CE certificate: May 26th, 2024

Signature of issuing person:

Position: Management representative
Date: 2021.5.1
Issue Place: Suzhou

Attachment A of Declaration of conformity

Product Name/ Models:

Product	Single Use Purse String Forceps
Models	PSF35(HJH 35), PSF55(HJH 55)

Attachment B of Declaration of conformity

Standards List

No.	Document Number	Version	Name of document
1	EN ISO 13485 (ISO 13485)	2016 (2016)	Medical devices. Quality management systems. Requirements for regulatory purposes
2	MDD93/42/EEC	2007	Medical Device Safety Directive
3	EN ISO 14971 (ISO 14971)	2019 (2019)	Medical Device -- Application of Risk Management for Medical Device
4	EN ISO 10993-1 (ISO 10993-1)	2009 (2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5	EN ISO 10993-5 (ISO 10993-5)	2009 (2009)	Biological Evaluation of Medical Device-Part 5: Test for Cytotoxicity: in vitro methods
6	EN ISO 10993-7 (ISO 10993-7)	2008 (2008)	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
7	EN ISO 10993-10 (ISO 10993-10)	2013 (2010)	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
8	EN ISO 10993-11 (ISO 10993-11)	2018 (2017)	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
9	EN ISO 15223-1 (ISO 15223-1)	2016 (2016)	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
10	ISO 15223-2	2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
11	EN 1041	2008	Information supplied by the manufacturer of medical devices
12	MEDDEV 2.7/1	Revision 4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
13	EN ISO 14155 (ISO 14155)	2011 (2011)	Clinical investigation of medical devices for human subjects -- Good clinical practice
14	EN ISO 11607-1 (ISO 11607-1)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 1:Requirements for materials,sterile barrier systems and packaging systems
15	EN ISO 11607-2 (ISO 11607-2)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 2:Validation requirements for forming,sealing and assembly processes
16	EN ISO 11135	2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine

	(ISO 11135)	(2014)	control of a sterilization process for medical devices
17	EN ISO 11737-1 (ISO 11737-1)	2018 (2018)	Sterilization of health care products. Microbiological methods. Part 1:Determination of a population of microorganisms on products
18	EN ISO 11737-2 (ISO 11737-2)	2009 (2019)	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
19	EN ISO 14644-1 (ISO 14644-1)	2015 (2015)	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
20	EN ISO 14644-2 (ISO 14644-2)	2015 (2015)	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
21	EN ISO 14630 (ISO 14630)	2012 (2012)	Non-active surgical implants -- General requirements
22	ASTM D4169	2016	Standard Practice for Performance Testing of Shipping Containers and Systems
23	IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices

Declaration of Conformity

Manufacturer:
Name: Suzhou Frankenman Medical Equipment Co., Ltd.
Address: 108 South Jinfeng Road, Suzhou High-New District, 215163 Suzhou, PEOPLE'S REPUBLIC OF CHINA
Tel: + 86-512-6878 0588/6878 0388
Fax: +86-512-6808 0025

European Representative:
Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175
Fax: 0049-40-255726

Product Name:
Single Use Endoscopic Linear Cutter Stapler and Reloads
Product code: See attachment A.
Product Classification: IIb
Rule of classification: Rule 8
GMDN Code: P45183
MD Code: MD 0302
Approach of product conformity verification: Annex II. Excluding (4)

We herewith declare that the above-mentioned products meet the provisions of the following EC MDD 93/42/EEC Council Directives and Standards. Suzhou Frankenman Medical Equipment Co., Ltd. is exclusively responsible for the DOC.

DIRECTIVES

General applicable directives:
Medical Device Directive: Council Directive MDD 93/42/EEC.
Standard:
All applicable harmonized Standards. See attachment B.

Notified Body: TüV SüD Product Service GmbH, Ridlerstraβe. 65, 80339 München, Germany
Identification Number: 0123
Certificate No: G1 091657 0014 Rev.02
Date of CE mark was affixed: May 9th, 2011
Expiration date of CE certificate: May 26th, 2024

Signature of issuing person:

SUZHOU FRANKENMAN MEDICAL EQUIPMENT CO., LTD. 苏州法兰克曼医疗器械有限公司 3205021913614

Position: Management representative
Date: 2021.5.17
Issue Place: Suzhou

Attachment A of Declaration of conformity

Product Name/ Models:

Product	Single Use Endoscopic Linear Cutter Stapler and Reloads
Models	Stapler: ELC 50, ELC 100, ELC 150, ELC 200, ELC 250, (HJN 50, HJN 100, HJN 150, HJN 200, HJN 250) Reloads: ESLCR 30M, ESLCR 30W, ESLCR 30B, ESLCR 30Y, ESLCR 30G, (HJNZ 30CB, HJNZ 30B, HJNZ 30Z, HJNZ 30S, HJNZ 30H) ESLCR 45M, ESLCR 45W, ESLCR 45B, ESLCR 45Y, ESLCR 45G, (HJNZ 45CB, HJNZ 45B, HJNZ 45Z, HJNZ 45S, HJNZ 45H) ESLCR 60M, ESLCR 60W, ESLCR 60B, ESLCR 60Y, ESLCR 60G, (HJNZ 60CB, HJNZ 60B, HJNZ 60Z, HJNZ 60S, HJNZ 60H) ECLCR 30M, ECLCR 30W, ECLCR 30B, ECLCR 30Y, ECLCR 30G, (HJNW 30CB, HJNW30B, HJNW30Z, HJNW 30S, HJNW 30H) ECLCR 45M, ECLCR 45W, ECLCR 45B, ECLCR 45Y, ECLCR 45G, (HJNW 45CB, HJNW 45B, HJNW 45Z, HJNW 45S, HJNW 45H) ECLCR 60M, ECLCR 60W, ECLCR 60B, ECLCR 60Y, ECLCR 60G (HJNW 60CB, HJNW 60B, HJNW 60Z, HJNW 60S, HJNW 60H)

Attachment B of Declaration of conformity

Standards List

No.	Document Number	Version	Name of document
1	EN ISO 13485 (ISO 13485)	2016 (2016)	Medical devices - Quality management system – for Regulatory Requirements
2	MDD93/42/EEC	2007	Medical Device Safety Directive
3	EN ISO 14971 (ISO 14971)	2019 (2019)	Medical devices -- Application of risk management to medical devices
4	EN ISO 10993-1 (ISO 10993-1)	2009 (2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5	EN ISO 10993-5 (ISO 10993-5)	2009 (2009)	Biological Evaluation of Medical Device-Part 5: Test for Cytotoxicity: in vitro methods
6	EN ISO 10993-10 (ISO 10993-10)	2013 (2010)	Biological Evaluation of Medical Device-Part 10: Test for Irritation and Sterilization
7	EN ISO 10993-11 (ISO 10993-11)	2018 (2017)	Biological evaluation of medical devices-Part 11: Tests for systemic toxicity
8	EN ISO 15223-1 (ISO 15223-1)	2016 (2016)	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
9	ISO 15223-2	2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
10	EN 1041	2008	Information supplied by the manufacturer of medical devices
11	MEDDEV 2.7/1	Revision 4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
12	EN ISO 14155 (ISO 14155)	2011 (2011)	Clinical investigation of medical devices for human subjects -- Good clinical practice
13	EN ISO 11607-1 (ISO 11607-1)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 1:Requirements for materials,sterile barrier systems and packaging systems
14	EN ISO 11607-2 (ISO 11607-2)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 2:Validation requirements for forming,sealing and assembly processes
15	EN ISO 11137-1 (ISO 11137-1)	2015 (2006)	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
16	EN ISO 11137-2 (ISO 11137-2)	2015 (2013)	Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose

17	EN ISO 11737-1 (ISO 11737-1)	2018 (2018)	Sterilization of health care products. Microbiological methods. Part 1:Determination of a population of microorganisms on products
18	EN ISO 11737-2 (ISO 11737-2)	2009 (2019)	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
19	EN ISO 14644-1 (ISO 14644-1)	2015 (2015)	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
20	EN ISO 14644-2 (ISO 14644-2)	2015 (2015)	Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
21	EN ISO 5832-2 (ISO 5832-2)	2018 (2018)	Implants for surgery. Metallic materials. Part 2:Unalloyed titanium
22	EN ISO 14630 (ISO 14630)	2012 (2012)	Non-active surgical implants -- General requirements
23	ASTM D4169	2016	Standard Practice for Performance Testing of Shipping Containers and Systems
24	IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices

Declaration of Conformity

Manufacturer:
Name: Suzhou Frankenman Medical Equipment Co., Ltd.
Address: 108 South Jinfeng Road, Suzhou High-New District, 215163 Suzhou, PEOPLE'S REPUBLIC OF CHINA
Tel: + 86-512-6878 0588/6878 0388
Fax: +86-512-6808 0025

European Representative:
Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175
Fax: 0049-40-255726

Product Name:
Disposable Alimentary Canal stapler/
Single Use Curved Intraluminal Circular Stapler,
Single Use Straight Intraluminal Circular Stapler

Product code: See attachment A.
Product Classification: IIb
Rule of classification: Rule 8
GMDN Code: P45183
MD Code: MD 0302
Approach of product conformity verification: Annex II. Excluding (4)

We herewith declare that the above-mentioned products meet the provisions of the following EC MDD 93/42/EEC Council Directives and Standards. Suzhou Frankenman Medical Equipment Co., Ltd. is exclusively responsible for the DOC.

DIRECTIVES

General applicable directives:
Medical Device Directive: Council Directive MDD 93/42/EEC.
Standard:
All applicable harmonized Standards. See attachment B.

Notified Body: TüV SüD Product Service GmbH, Ridlerstraβe. 65, 80339 München, Germany
Identification Number: 0123
Certificate No: G1 091657 0014 Rev.02
Date of CE mark was affixed: May 9th, 2011
Expiration date of CE certificate: May 26th, 2024

Signature of issuing person:
Position: Management representative
Date: 2021.5.17
Issue Place: Suzhou

Attachment A of Declaration of conformity

Product Name/ Models:

Product	Disposable Alimentary Canal stapler/ Single Use Curved Intraluminal Circular Stapler, Single Use Straight Intraluminal Circular Stapler
Models	CS21, CS25, CS28, CS32 CS21C, CS25C, CS28C, CS32C CS21L, CS25L, CS28L, CS32L CS21F, CS25F, CS28F, CS32F CS21CL, CS25CL, CS28CL, CS32CL, CS21S, CS25S, CS28S, CS32S, CS21CT, CS25CT, CS28CT, CS32CT, CS21CT/EA, CS25CT/EA, CS28CT/EA, CS32CT/EA

Attachment B of Declaration of conformity

Standards List

No.	Document Number	Version	Name of document
1	EN ISO 13485 (ISO 13485)	2016 (2016)	Medical devices - Quality management system – for Regulatory Requirements
2	MDD93/42/EEC	2007	Medical Device Safety Directive
3	EN ISO 14971 (ISO 14971)	2019 (2019)	Medical Device -- Application of Risk Management for Medical Device
4	EN ISO 10993-1 (ISO 10993-1)	2009 (2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5	EN ISO 10993-5 (ISO 10993-5)	2009 (2009)	Biological Evaluation of Medical Device-Part 5: Test for Cytotoxicity: in vitro methods
6	EN ISO 10993-10 (ISO 10993-10)	2013 (2010)	Biological Evaluation of Medical Device-Part 10: Test for Irritation and Sterilization
7	EN ISO 10993-11 (ISO 10993-11)	2018 (2017)	Biological evaluation of medical devices-Part 11: Tests for systemic toxicity
8	EN ISO 15223-1 (ISO 15223-1)	2016 (2016)	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
9	ISO 15223-2	2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
10	EN 1041	2008	Information supplied by the manufacturer of medical devices
11	MEDDEV 2.7/1	Revision 4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
12	EN 556-1:2001/AC:2006	2006	Sterilization of medical devices - Requirements for medical devices to be Sterilization of medical devices. Requirements for medical devices to be designated 'STERILE'. Part 1:Requirements for terminally sterilized medical devices
13	EN ISO 14155 (ISO 14155)	2011 (2011)	Clinical investigation of medical devices for human subjects -- Good clinical practice
14	EN ISO 11607-1 (ISO 11607-1)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 1:Requirements for materials,sterile barrier systems and packaging systems
15	EN ISO 11607-2 (ISO 11607-2)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 2:Validation requirements for forming,sealing and assembly processes

16	EN ISO 11137-1 (ISO 11137-1)	2015 (2006)	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
17	EN ISO 11137-2 (ISO 11137-2)	2015 (2013)	Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
18	EN ISO 11737-1 (ISO 11737-1)	2018 (2018)	Sterilization of health care products. Microbiological methods. Part 1:Determination of a population of microorganisms on products
19	EN ISO 11737-2 (ISO 11737-2)	2009 (2019)	Sterilization of Medical Device- Microorganisms Method-Part 2: Asepsis Test carried out during sterilization
20	EN ISO 14644-1 (ISO 14644-1)	2015 (2015)	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
21	EN ISO 14644-2 (ISO 14644-2)	2015 (2015)	Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
22	EN ISO 5832-2 (ISO 5832-2)	2018 (2018)	Implants for surgery. Metallic materials. Part 2:Unalloyed titanium
23	EN ISO 14630 (ISO 14630)	2012 (2012)	Non-active surgical implants -- General requirements
24	EN ISO 6507-1 (ISO 6507-1)	2018 (2018)	Metallic materials — Vickers hardness test — Part 1: Test method
25	ASTM D4169	2016	Standard Practice for Performance Testing of Shipping Containers and Systems
26	IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices

Declaration of Conformity

Manufacturer:
Name: Suzhou Frankenman Medical Equipment Co., Ltd.
Address: 108 South Jinfeng Road, Suzhou High-New District, 215163 Suzhou, PEOPLE'S REPUBLIC OF CHINA
Tel: + 86-512-6878 0588/6878 0388
Fax: +86-512-6808 0025

European Representative:
Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175
Fax: 0049-40-255726

Product Name:
Single Use Circular Stapler for Rectal Prolapse and Haemorrhoids
Product code: See attachment A.
Product Classification: IIb
Rule of classification: Rule 8
GMDN Code: P46737
MD Code: MD 0302
Approach of product conformity verification: Annex II. Excluding (4)

We herewith declare that the above-mentioned products meet the provisions of the following EC MDD 93/42/EEC Council Directives and Standards. Suzhou Frankenman Medical Equipment Co., Ltd. is exclusively responsible for the DOC.

DIRECTIVES

General applicable directives:
Medical Device Directive: Council Directive MDD 93/42/EEC.
Standard:
All applicable harmonized Standards. See attachment B.

Notified Body: TüV SüD Product Service GmbH, Ridlerstraβe. 65, 80339 München, Germany
Identification Number: 0123
Certificate No: G1 091657 0014 Rev.02
Date of CE mark was affixed: May 9th, 2011
Expiration date of CE certificate: May 26th, 2024

Signature of issuing person:

苏州法兰克曼医疗器械有限公司 SUZHOU FRANKENMAN MEDICAL EQUIPMENT CO., LTD. 3205021913614

Position: Management representative
Date: 2011.5.17
Issue Place: Suzhou

Attachment A of Declaration of conformity

Product Name/ Models:

Product	Single Use Circular Stapler for Rectal Prolapse and Haemorrhoids
Models	CPH30(HJZ30), CPH32(HJZ32), CPH34(HJZ34), CPH36(HJZ36), CPH30HV, CPH32HV, CPH34HV, CPH36HV, CPH34SMS, CPH36SMS CPH30ST/HJZ30ST CPH32ST/HJZ32ST CPH34ST/HJZ34ST CPH36ST/HJZ36ST CPH30HVST CPH32HVST CPH34HVST CPH36HVST STARR34 STARR36

Attachment B of Declaration of conformity - Standards List

No.	Document Number	Version	Name of document
1	EN ISO 13485 (ISO 13485)	2016 (2016)	Medical devices. Quality management systems. Requirements for regulatory purposes
2	MDD 93/42/EEC	2007	Medical Device Safety Directive
3	EN ISO 14971 (ISO 14971)	2019 (2019)	Medical devices -- Application of risk management to medical devices
4	EN ISO 10993-1 (ISO 10993-1)	2009 (2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5	EN ISO 10993-5 (ISO 10993-5)	2009 (2009)	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
6	EN ISO 10993-7 (ISO 10993-7)	2008 (2008)	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
7	EN ISO 10993-10 (ISO 10993-10)	2013 (2010)	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
8	EN ISO 10993-11 (ISO 10993-11)	2018 (2017)	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
9	EN ISO 15223-1 (ISO 15223-1)	2016 (2016)	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
10	ISO 15223-2	2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
11	EN 1041	2008	Information supplied by the manufacturer of medical devices
12	MEDDEV 2.7/1	Revision 4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
13	EN ISO 14155 (ISO 14155)	2011 (2011)	Clinical investigation of medical devices for human subjects -- Good clinical practice
14	EN ISO 11607-1 (ISO 11607-1)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 1:Requirements for materials,sterile barrier systems and packaging systems
15	EN ISO 11607-2 (ISO 11607-2)	2017 (2019)	Packaging for terminally sterilized medical devices. Part 2:Validation requirements for forming,sealing and assembly processes
16	EN ISO 11137-1 (ISO 11137-1)	2015 (2006)	Sterilization Of Health Care Products-Radiation-Part 1:Requirements For Development,Validation And Routine Control Of A Sterilization Process For Medical Devices

17	EN ISO 11137-2 (ISO 11137-2)	2015 (2013)	Sterilization Of Health Care Products-Radiation-Part 2:Establishing The Sterilization Dose
18	EN ISO 11737-1 (ISO 11737-1)	2018 (2018)	Sterilization of health care products. Microbiological methods. Part 1:Determination of a population of microorganisms on products
19	EN ISO 11737-2 (ISO 11737-2)	2009 (2019)	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
20	EN ISO 14644-1 (ISO 14644-1)	2015 (2015)	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
21	EN ISO 14644-2 (ISO 14644-2)	2015 (2015)	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
22	EN ISO 5832-2 (ISO 5832-2)	2018 (2018)	Implants for surgery. Metallic materials. Part 2:Unalloyed titanium
23	EN ISO 14630 (ISO 14630)	2012 (2012)	Non-active surgical implants -- General requirements
24	ASTM D4169	2016	Standard Practice for Performance Testing of Shipping Containers and Systems
25	IEC 62366-1	2015	Medical devices – Part 1: Application of usability engineering to medical devices
26	EN ISO 11135 (ISO 11135)	2014 (2014)	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

1 Declaration of Conformity

Manufacturer:

Name: Suzhou Frankenman Medical Equipment Co., Ltd.
Address: 108 South Jinfeng Road, Suzhou High-New District, 215163 Suzhou, PEOPLE'S REPUBLIC OF CHINA
Tel: + 86-512-6878 0588/6878 0388
Fax: +86-512-6808 0025

European Representative:

Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175
Fax: 0049-40-255726

Product Name: Single Use Anoscope Kit for CPH
Product code: See attachment A.
Product Classification: I*
Rule of classification: Rule 5
UMDNS Code: 10156
MD Code: MD 0106
Approach of product conformity verification: Annex V

We herewith declare that the above-mentioned product meets the provisions of the Council Directives EC (MDD 93/42/EEC） for medical devices and expected indications. All supporting documentations are certified by the company and the notified body, and the authenticity is committed. Suzhou Frankenman Medical Equipment Co., Ltd. is exclusively responsible for the DOC.

DIRECTIVES

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE MDD 93/42/EEC of medical devices (MDD 93/42/EEC) of 14 June 1993
Standard: All applicable harmonized Standards. See attachment B.
Notified Body: TüV SüD Product Service GmbH, Ridlerstraβe. 65, 80339 München, Germany
Identification Number: 0123
Certificate No: G2S 18 04 91657 012
Date of CE mark was affixed: July.29th, 2013
Expiration date of CE certificate: July. 28th, 2023
Signature of issuing person:

Position: Management representative
Date: May 20th, 2020
Issue Place: Suzhou

Attachment A of Declaration of conformity

Product Name/ Models:

Product	Single Use Anoscope Kit for CPH
Models	CK30M,CK32M,CK34M,CK36M,CK30F,CK32F,CK34F,CK36F

Essential Requirements Checklist

3.1 Harmonized standards list

No.	Document Number	Version	Name of document
1	EN ISO 13485 (ISO 13485)	2016 (2016)	Medical devices - Quality management system – for Regulatory Requirements
2	MDD93/42/EEC	2007	Medical Device Safety Directive
3	EN ISO 14971 (ISO 14971)	2019 (2019)	Medical Device -- Application of Risk Management for Medical Device
4	EN ISO 10993-1 (ISO 10993-1)	2009 (2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5	EN ISO 10993-5 (ISO 10993-5)	2009 (2009)	Biological Evaluation of Medical Device-Part 5: Test for Cytotoxicity: in vitro methods
6	EN ISO 10993-10 (ISO 10993-10)	2013 (2010)	Biological Evaluation of Medical Device-Part 10: Test for Irritation and Sterilization
7	EN ISO 10993-11 (ISO 10993-11)	2018 (2017)	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
8	EN ISO 15223-1 (ISO 15223-1)	2016 (2016)	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
9	ISO 15223-2	2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
10	EN 1041	2008	Information supplied by the manufacturer of medical devices
11	MEDDEV 2.7/1	Revision 4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
12	EN ISO 14155 (ISO 14155)	2011 (2011)	Clinical investigation of medical devices for human subjects -- Good clinical practice
13	EN ISO 11607-1 (ISO 11607-1)	2017 (2019)	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
14	EN ISO 11607-2 (ISO 11607-2)	2017 (2019)	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

15	EN ISO 11137-1 (ISO 11137-1)	2015 (2006)	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
16	EN ISO 11137-2 (ISO 11137-2)	2015 (2013)	Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
17	EN ISO 11737-1 (ISO 11737-1)	2018 (2018)	Sterilization of Medical Device-Microorganisms Method-Part 1 Determination of the Microorganisms on Products
18	EN ISO 11737-2 (ISO 11737-2)	2009 (2019)	Sterilization of Medical Device- Microorganisms Method-Part 2: Asepsis Test carried out during sterilization
19	EN ISO 14644-1 (ISO 14644-1)	2015 (2015)	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
20	EN ISO 14644-2 (ISO 14644-2)	2015 (2015)	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
21	ASTM D4169	2016	Standard Practice for Performance Testing of Shipping Containers and Systems
22	IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices

DalimsurgNET
a member of the Frankenman Group

CE 1639

DECLARATION OF CONFORMITY

(Manufacturer's Declaration)

This Declaration of Conformity is only valid with record of final inspection for a specific lot./device enclosed.

MANUFACTURER	**dalim SurgNET Corporation** B-708, 1002 Woolim Blue nine, 583, Yangcheon-ro, Gangseo-gu, Seoul 07547, Korea Telephone +82 2 2093 7888 Fax +82 2 2093 7889
EUROPEAN REPRESENTATIVE:	**MERIDIUS MEDICAL EUROPE LIMITED.** Unit 3D, North Point House, North point Business Park, New Mallow Road, CORK, Ireland Telephone +353 212066448
DEVICE CLASSIFICATION NAME	Sterile single-use access port for laparoscopic surgery
MODEL/TYPE:	TRANSPORT *Refer to the attachment #1.*
CLASSIFICATION:	Ⅱa
RULE TO BE APPLIED:	7
CONFORMITY ASSESSMENT ROUT:	Annex Ⅱ excluding section 4

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC(As amended by 2007/47/EC) FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:	*Refer to the attachment #2.*
NOTIFIED BODY (EC) CERTIFICATE(S):	**SGS** SGS House Noorderlaan 87 2030 Antwerp Belgium
START OF CE-MARKING PLACE, DATE OF ISSUE:	In Seoul, 2010-12-27
SIGNATURE:	Yuanchao Wang President

Attachment #1.

List of CE Marked Product List

Updated Oct 10, 2020 (Rev 5)

DEVICE CLASSIFICATION NAME: Sterile single-use access port for laparoscopic surgery

TRADE NAME: TRANSPORT

EC-CERTIFICATE No.: KR19/81826219

No.	Model/type	Classification	Rule to be applied	Conformity Assessment route	GMDN Code	Start of CE Marking
1	TRANSPORT (TR05F)	IIa	7	Annex Ⅱ exduding section 4	14155	2010-12-27
2	TRANSPORT (TR05FL)	IIa	7	Annex Ⅱ exduding section 4	14155	2010-12-27
3	TRANSPORT (TR05FL110)	IIa	7	Annex Ⅱ exduding section 4	14155	2012-01-16
4	TRANSPORT (TR03)	IIa	7	Annex Ⅱ exduding section 4	14155	2013-05-02
5	TRANSPORT (Tport05)	IIa	7	Annex Ⅱ exduding section 4	14155	2013-05-02
6	TRANSPORT (Tport10)	IIa	7	Annex Ⅱ exduding section 4	14155	2015-08-10
7	TRANSPORT (Tport12)	IIa	7	Annex Ⅱ exduding section 4	14155	2015-08-10
8	TRANSPORT (TR10F)	IIa	7	Annex Ⅱ exduding section 4	14155	2013-05-02
9	TRANSPORT (TR10FL)	IIa	7	Annex Ⅱ exduding section 4	14155	2015-08-10
10	TRANSPORT (TR10FL150)	IIa	7	Annex Ⅱ exduding section 4	14155	2015-08-10
11	TRANSPORT (TR12F)	IIa	7	Annex Ⅱ exduding section 4	14155	2013-05-02
12	TRANSPORT (TR12FL)	IIa	7	Annex Ⅱ exduding section 4	14155	2015-08-10
13	TRANSPORT (TR12FL150)	IIa	7	Annex Ⅱ exduding section 4	14155	2015-08-10
14	TRANSPORT (TR03C)	IIa	7	Annex Ⅱ exduding section 4	14155	2015-08-10
15	TRANSPORT (TR05FC)	IIa	7	Annex Ⅱ exduding section 4	14155	2015-08-10
16	TRANSPORT (TR05FLC)	IIa	7	Annex Ⅱ exduding section 4	14155	2015-08-10
17	TRANSPORT (TR05FL110C)	IIa	7	Annex Ⅱ exduding section 4	14155	2015-08-10

18	TRANSPORT (TR10FC)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
19	TRANSPORT (TR10FLC)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
20	TRANSPORT (TR10FL15C)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
21	TRANSPORT (TR12FC)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
22	TRANSPORT (TR12FLC)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
23	TRANSPORT (TR12FL150C)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
24	TRANSPORT (Tport05C)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
25	TRANSPORT (Tport10C)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
26	TRANSPORT (Tport12C)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
27	TRANSPORT (TR03-D)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
28	TRANSPORT (TR05F-D)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
29	TRANSPORT (TR05FL-D)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
30	TRANSPORT (TR05FL110-D)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
31	TRANSPORT (TR10F-D)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
32	TRANSPORT (TR10FL-D)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
33	TRANSPORT (TR10FL150-D)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
34	TRANSPORT (TR12F-D)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
35	TRANSPORT (TR12FL-D)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
36	TRANSPORT (TR12FL150-D)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
37	TRANSPORT (Tport05-D)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
38	TRANSPORT (Tport10-D)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10
39	TRANSPORT (Tport12-D)	IIa	7	Annex Ⅱ excluding section 4	14155	2015-08-10

Prepared by Bomi Joo _____ / Approved by Yuanchao Wang _____

cf. Notified Body is SGS, identification no. 1639

Attachment 2.

European Norms and Standards and other Documents supporting Technical Files

- **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 1041:2008**, Information supplied by the manufacturer with medical devices
- **EN ISO 10993-5**, Tests for in vitro cytotoxicity - Test on extracts method
- **EN ISO 10993-10**, Tests for irritation and skin sensitization - Guinea pig Maximization test「GPMT」
- **EN ISO 10993-10**, Tests for irritation and skin sensitization - Intracutaneous (Intradermal) reactivity test
- **EN ISO 10993-11**, Tests for systemic toxicity - Acute Systemic Toxicity
- USP <151> Pyrogen Test
- The Korean Pharmacopeia/ General Requirements for Tests and Assays/ Sterility Test
- **EN ISO 11137-1:2015**, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of sterilization process for medical devices
- **EN ISO 11137-2:2015**, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
- **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**, Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
- **MEDDEV. 2.7.1 Rev4**, Clinical evaluation: Guide for manufacturers and notified bodies
- **EN ISO 13485:2016**, Medical Devices – Quality Management Systems – Requirement for Regulatory Purpose

- **ISO 14644-1:2015**, Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration
- **ISO 14644-2:2015**, Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
- **EN ISO 14971:2012**, Medical devices – Application of risk management to medical devices
- **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
- **ASTM F 1980-07,** Shelf life test

DalimsurgNET
a member of the Frankenman Group

CE
1639

DECLARATION OF CONFORMITY

(Manufacturer's Declaration)

This Declaration of Conformity is only valid with record of final inspection for a specific lot./device enclosed.

MANUFACTURER	**dalim SurgNET Corporation** B-708, 1002, Woolim Blue nine, 583, Yangcheon-ro, Gangseo-gu, Seoul 07547, Korea Telephone +82 2 2093 7888 Fax +82 2 2093 7889
EUROPEAN REPRESENTATIVE:	**MERIDIUS MEDICAL EUROPE LIMITED.** Unit 3D, North Point House, North point Business Park, New Mallow Road, CORK, Ireland Telephone +353 212066448
PRODUCT:	Sterile single-use access port for laparoscopic surgery and breast surgery
MODEL/TYPE:	OCTO™ *Refer to the attachment #1.*
CLASSIFICATION:	Ⅱa
RULE TO BE APPLIED:	7
CONFORMITY ASSESSMENT ROUT:	Annex Ⅱ excluding section 4

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC(As amended by 2007/47/EC) FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:	*Refer to the attachment #2.*
NOTIFIED BODY (EC) CERTIFICATE(S):	**SGS** SGS House Noorderlaan 87 2030 Antwerp Belgium
START OF CE-MARKING PLACE, DATE OF ISSUE:	In Seoul, 2009-09-15
SIGNATURE:	Yuanchao Wang President

Attachment #1.

List of CE Marked Product List

Updated Jan 1st, 2020 (Rev 6)

PRODUCT NAME: Sterile single-use access port for laparoscopic surgery and breast surgery

TRADE NAME: OCTO™

EC-CERTIFICATE No.: KR19/81826219

No.	Model/type	Classification	Rule to be applied	Conformity Assessment route	GMDN Code	Start of CE Marking
1.	OCTO Port(OT501I)	IIa	7	Annex Ⅱ excluding section 4	13375	2009-09-15
2.	OCTO Port(OT301I)	IIa	7	Annex Ⅱ excluding section 4	13375	2009-09-15
3.	OCTO Port(OT501SI)	IIa	7	Annex Ⅱ excluding section 4	13375	2009-09-15
4.	OCTO Port(OT303SI-A)	IIa	7	Annex Ⅱ excluding section 4	13375	2009-09-15
5.	OCTO Port(OT303SI-B)	IIa	7	Annex Ⅱ excluding section 4	13375	2009-09-15
6	OCTO Port(OT303SI-C)	IIa	7	Annex Ⅱ excluding section 4	13375	2009-09-15
7.	OCTO Port(OT303SI-D)	IIa	7	Annex Ⅱ excluding section 4	13375	2009-09-15
8.	OCTO Port(OT501S2I)	IIa	7	Annex Ⅱ excluding section 4	13375	2010-07-29
9.	OCTO Port(OT301S2I)	IIa	7	Annex Ⅱ excluding section 4	13375	2010-07-29
10.	OCTO Port(OT303V2I)	IIa	7	Annex Ⅱ excluding section 4	13375	2010-07-29
11.	OCTO Port(OT503V2I)	IIa	7	Annex Ⅱ excluding section 4	13375	2010-07-29

12.	OCTO Port(OT304V2I-A)	IIa	7	Annex Ⅱ excluding section 4	13375	2010-07-29
13.	OCTO Port(OT504V2I-A)	IIa	7	Annex Ⅱ excluding section 4	13375	2010-07-29
14.	OCTO Port(OT304V2I-B)	IIa	7	Annex Ⅱ excluding section 4	13375	2010-07-29
15.	OCTO Port(OT504V2I-B)	IIa	7	Annex Ⅱ excluding section 4	13375	2010-07-29
16.	OCTO Port(OT501LI)	IIa	7	Annex Ⅱ excluding section 4	13375	2011-03-28
17.	OCTO Port(OT501S2LI)	IIa	7	Annex Ⅱ excluding section 4	13375	2011-03-28
18.	OCTO Port(OT503V2LI)	IIa	7	Annex Ⅱ excluding section 4	13375	2011-03-28
19.	OCTO Port(OT504V2LI-A)	IIa	7	Annex Ⅱ excluding section 4	13375	2011-03-28
20.	OCTO Port(OT504V2LI-B)	IIa	7	Annex Ⅱ excluding section 4	13375	2011-03-28
21.	OCTO Port(OT303V2NI)	IIa	7	Annex Ⅱ excluding section 4	13375	2014-01-17
22.	OCTO Port(OT503V2NI)	IIa	7	Annex Ⅱ excluding section 4	13375	2014-01-17
23.	OCTO Port(OT503V2LNI)	IIa	7	Annex Ⅱ excluding section 4	13375	2014-01-17
24.	OCTO Port(OT303V2-OMC)	IIa	7	Annex Ⅱ excluding section 4	13375	2017-01-03
25.	OCTO Port(OT503V2-OMC)	IIa	7	Annex Ⅱ excluding section 4	13375	2017-01-03

Prepared by Yiseul Kang _____ / Approved by Yuanchao Wang

cf. Notified Body is SGS, identification no. 1639

Attachment #2.

European Norms and Standards and other Documents supporting Technical Files

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 1041:2008, Information supplied by the manufacturer with medical devices

EN ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing

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

EN ISO 10993-10:2009, 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 11137-1:2015, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of sterilization process for medical devices

EN ISO 11137-2:2015, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose

MEDDEV. 2.7.1 Rev4, Clinical evaluation: Guide for manufacturers and notified bodies

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, Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products

EN ISO 13485:2016, Medical Devices – Quality Management Systems – Requirement for Regulatory Purpose

ISO 14644-1:2015, Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness

ISO 14644-2:2015, Cleanrooms and associated controlled environments – Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1

EN ISO 14971:2012, Medical devices – Application of risk management to medical devices

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 091657 0013 Rev. 02

Holder of Certificate: **Suzhou Frankenman Medical Equipment Co., Ltd.**
108 South Jinfeng Road
Suzhou High-New District
215163 Suzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution of Disposable Alimentary Canal Staplers/ Single Use Curved Intraluminal Circular Staplers, Disposable Reloadable Linear Staplers and Reloads/ Single Use Reloadable Linear Staplers and Reloads, Disposable Reloadable Linear Cutter Stapler and Reloads/ Single Use Reloadable Linear Cutter Stapler and Reloads, Single Use Circular Staplers for Rectal Prolapse and Haemorrhoids, Single Use Transverse Cutting Linear Staplers and Reloads, Single Use Endoscopic Linear Cutter Stapler and Reloads, Single Use Straight Intraluminal Circular Stapler, Single Use Suction and Irrigation System, Single Use Anoscope Kits for CPH, Single Use Purse String Forceps, Anvil Grasping Forceps, Lumen Sizer Kit, Single Use Endoscopic Multiple Instrument Access Port, Ultrasonic Soft Tissue Cutting and Sealing System, Single Use Endoscopic Linear Stapler, Disposable Laparoscopic Trocar, Single Use Endoscopic Linear Cutter Stapler and Reloads, Disposable Polypectomy Snares, Disposable Injection Therapy Needle Catheter, Disposable Endoscopic Biopsy Forceps, Single Use Ultrasound Activated Scalpel (Shear)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 091657 0013 Rev. 02

Report No.:	SH2008702
Valid from:	2021-04-26
Valid until:	2023-06-11

Date, 2021-04-26

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 091657 0013 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Suzhou Frankenman Medical Equipment Co., Ltd.
108 South Jinfeng Road, Suzhou High-New District, 215163
Suzhou, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

America

CERTIFICATE

No. QS5 091657 0015 Rev. 00

Certificate Holder:

Suzhou Frankenman Medical Equipment Co., Ltd.
108 South Jinfeng Road
Suzhou High-New District
215163 Suzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate:

Design and Development, Production, Distribution of Disposable Alimentary Canal Staplers / Single Use Curved Intraluminal Circular Staplers, Disposable Reloadable Linear Staplers and Reloads / Single Use Reloadable Linear Staplers and Reloads, Disposable Reloadable Linear Cutter Stapler and Reloads / Single Use Reloadable Linear Cutter Stapler and Reloads, Single Use Circular Staplers for Rectal Prolapse and Haemorrhoids, Single Use Transverse Cutting Linear Staplers and Reloads, Single Use Endoscopic Linear Cutter Stapler and Reloads, Single Use Straight Intraluminal Circular Stapler, Single Use Suction and Irrigation System, Single Use Anoscope Kits for CPH, Single Use Purse String Forceps, Anvil Grasping Forceps, Lumen Sizer Kit, Single Use Endoscopic Multiple Instrument Access Port

Standard(s): **ISO 9001:2015**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **SH2008701**

Effective Date: **2020-07-30**

Expiry Date: **2023-05-31**

Date of Issue: 2020-08-07

Tina Israel
Manager, US Certification Body,
Medical and Health Services

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