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:

Position: Management representative Date: ۲، الحر Issue Place: Suzhou Title: DOC Doc. No



Doc. No.: CE00006-01

Ver.: A/7

Page 1 of 4

Schedule A of Declaration of conformity Product Name/ Models:

TTOULUCE INA	ine/ 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

Т

	Standards List		
	No. Document Numb	er Versio	n Name of document
	1 EN ISO 13485	2016	6 Medical devices. Quality management systems. Requirement
-	(ISO 13485)	(2016	b) for regulatory purposes
	2 MDD 93/42/EEC	2007	
	3 EN ISO 14971	2019	
\vdash	(ISO 14971)	(2019	devices
	4 EN ISO 10993-1	2009	Difference and an on medical devices - Part 1: Evaluation
 	(ISO 10993-1)	(2018)	
	5 EN ISO 10993-5	2009	Biological evaluation of medical devices Part 5: Tests for in
	(ISO 10993-5)	(2009)	
6	EN ISO 10993-10	2013	Biological evaluation of medical devices Part 10: Tests for
	(ISO 10993-10)	(2010)	
7	EN ISO 10993-11	2018	Biological evaluation of medical devices — Part 11: Tests for
	(ISO 10993-11)	(2017)	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	2011	Clinical investigation of medical devices for human subjects
	(ISO 14155)	(2011)	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
10	EN ISO 11137-2	2015	Sterilization Of Health Care Products-Radiation-Part
16	(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	(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

Sauser the

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:

Position: Management representativ Date: العدالاهر) Issue Place: Suzhou



Title: Declaration of Conformity

Document No.: CE00007-01

Version: A/7

Product Na	ame/ 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 A of Declaration of conformity Product Name/ Models:

Attachment B of Declaration of conformity

Standards List

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

17	EN ISO 11737-1	2018	Sterilization of Medical Device-Microorganisms Method-
17	(ISO 11737-1)	(2018)	Part 1 Determination of the Microorganisms on Products
18	EN ISO 11737-2	2009	Sterilization of Medical Device- Microorganisms
18	(ISO 11737-2)	(2019)	Method-Part 2: Asepsis Test carried out during sterilization
	EN ISO 14644-1	2015	Cleanrooms and associated controlled environments
19	(ISO 14644-1)	2015 (2015)	Part 1: Classification of air cleanliness by particle
	(130 14044-1)	(2010)	concentration
			Cleanrooms and associated controlled environments
20	EN ISO 14644-2	2015	Part 2: Monitoring to provide evidence of cleanroom
20	(ISO 14644-2)	(2015)	performance related to air cleanliness by particle
1			concentration
21	EN ISO 14630	2012	
21	(ISO 14630)	(2012)	Inactive surgical implants-general requirements
22	ASTM D4169	2017	Standard Practice for Performance Testing of Shipping
		2016	Containers and Systems
23	IEC 62366-1	2015	Medical devices - Part 1: Application of usability
2.5	120 02500-1	2013	engineering to medical devices

Suzhou Frankenman Medical Equipment Co., Ltd

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 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, Ridlerstraße. 65, 80339 München,

Germany

Identification Number: 0123

Certificate No: G1 091657 0014 Rev.02

Date of CE mark was affixed: N

Expiration date of CE certificate: May

Signature of issuing person:

Position: Management representative Date: ノーノ・ノー Issue Place: Suzhou Title: DOC Doc. No



Doc. No.: CE00002-01 Ver.: A/7

7 Pa

Attachment A of Declaration of conformity

	me/ Models:			
Braduat Disposable Reloadable Linear Stapler and Reloads/				
Product	Single use Reloadable Linear Stapler and Reloads			
	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)			
Models	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)			
İ	LSR 60G(HJFZ60H)			
	LSR 90B(HJFZ90Z)			
	LSR 90Y(HJFZ90S)			
	LSR 90G(HJFZ90H)			

Attachment B of Declaration of conformity Standards List

	ndards 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
	EN ISO 14971	2019	Medical devices Application of risk management to medical
3	(ISO 14971)	(2019)	devices
4	EN ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
L	(ISO 10993-1)	(2018)	
5	EN ISO 10993-5	2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
	(ISO 10993-5)	(2009)	vite cytoloxicity
6	EN ISO 10993-10	2013	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
	(ISO 10993-10)	(2010)	initiation and skin sensitization
7	EN ISO 10993-11	2018	Biological evaluation of medical devices — Part 11: Tests for
	(ISO 10993-11)	(2017)	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
	EN ISO 14155	2011	Clinical investigation of medical devices for human subjects
12	(ISO 14155)	(2011)	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
m 1.1	DOC		

Doc. No.: CE00002-01 Ver.: A/7 Page 3 of 4

	(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

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, Ridlerstraße. 65, 80339 München, Germany

Identification Number: 0123

Certificate No: G1 091657 0014 Rev.02

Date of CE mark was affixed:

Expiration date of CE certificate: May

Signature of issuing person:

Position: Management representative Date: אין אין אין Issue Place: Suzhou



Title: DOC

Doc. No.: CE00003-01

-01 Ver.: A/7

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
	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)
Models	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
ſ	HJQZ60B/Z/S/H
	LCR 80W/B/Y/G

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

No			conformity - Standards List
		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
	EN ISO 14971	2019	Medical devices Application of risk management to medical
3	(ISO 14971)	(2019)	devices
4	EN ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation
 	(ISO 10993-1)	(2018)	and testing within a risk management process
5	EN ISO 10993-5	2009	Biological evaluation of medical devices Part 5: Tests for in
	(ISO 10993-5)	(2009)	vitro cytotoxicity
6	EN ISO 10993-10	2013	Biological evaluation of medical devices Part 10: Tests for
	(ISO 10993-10)	(2010)	irritation and skin sensitization
7	EN ISO 10993-11	2018	Biological evaluation of medical devices — Part 11: Tests for
	(ISO 10993-11)	(2017)	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
10	EN ISO 14155	2011	Clinical investigation of medical devices for human subjects
12	(ISO 14155)	(2011)	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

Attachment B of Declaration of conformity - Standards List

Title: DOC

Doc. No.: CE00003-01 Ver.: A/7 Page 4 of 5

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

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

M

Identification Number: 0123

Certificate No: G1 091657 0014 Rev.02 Date of CE mark was affixed: May 9th

Expiration date of CE certificate:

Signature of issuing person:

Position: Management representative Date: اربر إلاصر Issue Place: Suzhou

Doc. No.: CE00009-01

Page 1 of 4

Attachment A of Declaration of conformity

Product Name/ Models:				
ĺ	Product	Single Use Purse String Forceps		
ľ	Models	PSF35(HJH 35), PSF55(HJH 55)		

Attachment B of Declaration of conformity Standards List

	dards 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
	EN ISO 14971	2019	Medical Device Application of Risk Management for
3	(ISO 14971)	(2019)	Medical Device
4	EN ISO 10993-1	2009 (2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
	(ISO 10993-1)	(2016)	
5	EN ISO 10993-5	2009	Biological Evaluation of Medical Device-Part 5: Test for Cytotoxicity: in vitro methods
	(ISO 10993-5)	(2009)	Cytotokieky, m the mono-2
6	EN ISO 10993-7	2008	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
	(ISO 10993-7)	(2008)	
7	EN ISO 10993-10	2013	Biological evaluation of medical devices Part 10: Tests for
	(ISO 10993-10)	(2010)	irritation and skin sensitization
8	EN ISO 10993-11	2018	Biological evaluation of medical devices — Part 11: Tests
	(ISO 10993-11)	(2017)	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
	EN ISO 14155	2011	Clinical investigation of medical devices for human subjects
13	(ISO 14155)	(2011)	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

Suzhou Frankenman Medical Equipment Co., Ltd.

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, Ridlerstraße. 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: ا. د. لرمز Issue Place: Suzhou Title: DOC Doc.



Doc. No.: CE00008-01

Ver.: A/7

Attachment A of Declaration of conformity Product Name/ Models:

FIGURE INS	Product Name/ Models:						
Product	Single Use Endoscopic Linear Cutter Stapler and Reloads						
	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,						
Models	(HJNZ 45CB, HJNZ 45B, HJNZ 45Z, HJNZ 45S, HJNZ 45H)						
11104013	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

—	andards List	- <u></u>	· · · · · · · · · · · · · · · · · · ·
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	2019	Medical devices Application of risk management to medical
	(ISO 14971)	(2019)	devices
4	EN ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation
	(ISO 10993-1)	(2018)	and testing within a risk management process
5	EN ISO 10993-5	2009	Biological Evaluation of Medical Device-Part 5: Test for
	(ISO 10993-5)	(2009)	Cytotoxicity: in vitro methods
6	EN ISO 10993-10	2013	Biological Evaluation of Medical Device-Part 10: Test for Irritation and Sterilization
	(ISO 10993-10)	(2010)	Inflation and Sternization
7	EN ISO 10993-11	2018	Biological evaluation of medical devices-Part 11: Tests for
	(ISO 10993-11)	(2017)	systemic toxicity
8	EN ISO 15223-1 (ISO 15223-1)	2016	Medical devices Symbols to be used with medical device labels, labelling and information to be supplied Part 1:
	(130 13223-1)	(2016)	General requirements
9	ISO 15223-2	2010	Medical devices Symbols to be used with medical device
-		2010	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
		<u> </u>	CLINICAL EVALUATION:
11	MEDDEV 2 7/1	Revision	A GUIDE FOR MANUFACTURERS AND NOTIFIED
11	MEDDEV 2.7/1	4	BODIES
			UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
12	EN ISO 14155	2011	Clinical investigation of medical devices for human subjects
	(ISO 14155)	(2011)	Good clinical practice
	EN ISO 11607-1	2017	Packaging for terminally sterilized medical devices. Part
13	(ISO 11607-1)		1:Requirements for materials, sterile barrier systems and
	(150/1100/-1)	(2019)	packaging systems
	EN ISO 11607-2	2017	Packaging for terminally sterilized medical devices. Part
14	(ISO 11607-2)	(2019)	2: Validation requirements for forming, sealing and assembly
		(2019)	processes
	EN ISO 11137-1	2015	Sterilization of health care products Radiation Part 1:
15	(ISO 11137-1)	(2006)	Requirements for development, validation and routine control
		(2000)	of a sterilization process for medical devices
16	EN ISO 11137-2	2015	Sterilization of health care products Radiation Part 2:
	(ISO 11137-2)	(2013)	Establishing the sterilization dose
Intle:	DOC	Doc	. No.: CE00008-01 Ver.: A/7 Page 3 of 4

24	IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices
23	ASTM D4169	2016	Standard Practice for Performance Testing of Shipping Containers and Systems
22	EN ISO 14630 (ISO 14630)	2012 (2012)	Non-active surgical implants General requirements
21	EN ISO 5832-2 (ISO 5832-2)	2018 (2018)	Implants for surgery. Metallic materials. Part 2:Unalloyed titanium
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
19	EN ISO 14644-1 (ISO 14644-1)	2015 (2015)	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration
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
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

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, Ridlerstraße. 65, 80339 München, Germany

Identification Number: 0123

Certificate No: G1 091657 0014 Rev.02

Date of CE mark was affixed:

Expiration date of CE certificate: May 26

Signature of issuing person: Position: Management representative Date: ۲۰۱۲ Issue Place: Suzhou

Title: Declaration of Conformity



Doc. No.: CE00001-01

Ver.: A/7

Attachment A of Declaration of conformity Product Name/ Models:

Product Na	me/ Models:
	Disposable Alimentary Canal stapler/
Product	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,
	CS213, CS253, CS253, CS525, CS21CT, CS25CT, CS28CT, CS32CT, CS21CT/EA, CS25CT/EA, CS28CT/EA, CS32CT/EA

Attachment B of Declaration of conformity

indards List		5
. Document Number	Version	Name of document
EN ISO 13485 (ISO 13485)	2016 (2016)	Medical devices - Quality management system – for Regulatory Requirements
MDD93/42/EEC	2007	Medical Device Safety Directive
EN ISO 14971 (ISO 14971)	2019 (2019)	Medical Device Application of Risk Management for Medical Device
EN ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation
(ISO 10993-1)	(2018)	and testing within a risk management process
EN ISO 10993-5	2009	Biological Evaluation of Medical Device-Part 5: Test for
(ISO 10993-5)	(2009)	Cytotoxicity: in vitro methods
EN ISO 10993-10	2013	Biological Evaluation of Medical Device-Part 10: Test for
(ISO 10993-10)	(2010)	Irritation and Sterilization
EN ISO 10993-11	2018	Biological evaluation of medical devices-Part 11: Tests for
(ISO 10993-11)	(2017)	systemic toxicity
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
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
EN 1041	2008	Information supplied by the manufacturer of medical devices
MEDDEV 2.7/1	Revision 4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
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
EN ISO 14155 (ISO 14155)	2011 (2011)	Clinical investigation of medical devices for human subjects Good clinical practice
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
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
	 Document Number EN ISO 13485 (ISO 13485) MDD93/42/EEC EN ISO 14971 (ISO 14971) EN ISO 10993-1 (ISO 10993-1) EN ISO 10993-5) (ISO 10993-5) EN ISO 10993-10 (ISO 10993-10) EN ISO 10993-11 (ISO 10993-11) EN ISO 15223-1 (ISO 15223-1) ISO 15223-2 EN 1041 MEDDEV 2.7/1 EN ISO 14155 (ISO 14155) EN ISO 11607-1 (ISO 11607-1) EN ISO 11607-2 	Document Number Version EN ISO 13485 (ISO 13485) 2016 (2016) MDD93/42/EEC 2007 EN ISO 14971 2019 (ISO 14971) ISO 14971 2009 (ISO 10993-1) 2009 ISO 10993-1) (2018) EN ISO 10993-5) 2009 ISO 10993-10 (2009) ISO 10993-10 (2010) EN ISO 10993-10 (2010) EN ISO 10993-10 (2017) EN ISO 10993-11 2018 (ISO 10993-11) (2017) EN ISO 15223-1 2016 (ISO 15223-1) 2016 (ISO 15223-1) 2010 ISO 15223-2 2010 EN 1041 2008 MEDDEV 2.7/1 Revision 4 S56-1:2001/AC:2006 2006 EN ISO 14155 2011 (ISO 14155) 2017 EN ISO 11607-1 2017 EN ISO 11607-2 2017

Ver.: A/7

<u> </u>			
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	2015	Sterilization of health care products Radiation Part 2:
	(ISO 11137-2)	(2013)	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	2009	Sterilization of Medical Device- Microorganisms
	(ISO 11737-2)	(2019)	Method-Part 2: Asepsis Test carried out during sterilization
20	EN ISO 14644-1	2015	Cleanrooms and associated controlled environments Part
20	(ISO 14644-1)	(2015)	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	2018	Implants for surgery. Metallic materials. Part 2:Unalloyed
	(ISO 5832-2)	(2018)	titanium
23	EN ISO 14630	2012	
	(ISO 14630)	(2012)	Non-active surgical implants General requirements
24	EN ISO 6507-1	2018	Metallic materials — Vickers hardness test — Part 1: Test
<u> </u>	(ISO 6507-1)	(2018)	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

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, Ridlerstraße. 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 representativ Date: ۲۰۱۶ Issue Place: Suzhou

Title: Declaration of Conformity



Doc. No.: CE00004-01 Ver.: A/7

Attachment A of Declaration of conformity

Product Na	ame/ 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 CPH30HVST CPH32HVST CPH34HVST CPH36HVST STARR34 STARR36						

Ver.: A/7

No		Version	Name of degree and the second
			Name of document
1	EN ISO 13485 (ISO 13485)	2016 (2016)	Medical devices. Quality management systems. Requirements
2	MDD 93/42/EEC		for regulatory purposes
		2007	Medical Device Safety Directive
3	EN ISO 14971	2019	Medical devices Application of risk management to medical
├	(ISO 14971)	(2019)	devices
4	EN ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
	(ISO 10002 1)	(2018)	
	(ISO 10993-1)	(2010)	
5	EN ISO 10993-5	2009	Biological evaluation of medical devices Part 5: Tests for in
	(ISO 10993-5)	(2009)	vitro cytotoxicity
	(100 10995-5)	(2009)	
6	EN ISO 10993-7	2008	Biological evaluation of medical devices Part 7: Ethylene
	(ISO 10993-7)	(2008)	oxide sterilization residuals
┣──		(2000)	
7	EN ISO 10993-10	2013	Biological evaluation of medical devices Part 10: Tests for
ĺ ′	(ISO 10993-10)	(2010)	irritation and skin sensitization
	(150 10))5-10)	(2010)	
8	EN ISO 10993-11	2018	Biological evaluation of medical devices — Part 11: Tests for
	(ISO 10993-11)	(2017)	systemic toxicity
		(Medical devices Symbols to be a literated
9	EN ISO 15223-1	2016	Medical devices Symbols to be used with medical device
-	(ISO 15223-1)	(2016)	labels, labelling and information to be supplied Part 1: General requirements
	ISO 15223-2	· · · · ·	Medical devices Symbols to be used with medical device
10		2010	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
			CLINICAL EVALUATION:
	MEDDEV 2.7/1	Revision 4	A GUIDE FOR MANUFACTURERS AND NOTIFIED
12			BODIES
			UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
12	EN ISO 14155	2011	Clinical investigation of medical devices for human subjects
13	(ISO 14155)	(2011)	Good clinical practice
	EN 180 11607 1		Packaging for terminally sterilized medical devices. Part
14	EN ISO 11607-1 (ISO 11607-1)	2017	1:Requirements for materials, sterile barrier systems and
		(2019)	packaging systems
15	EN ISO 11607-2	2017	Packaging for terminally sterilized medical devices. Part
		2017	2:Validation requirements for forming, sealing and assembly
	(ISO 11607-2)	(2019)	processes
16	EN ISO 11137-1	2015	Sterilization Of Health Care Products-Radiation-Part
	(ISO 11137-1)	(2006)	1:Requirements For Development, Validation And Routine
	((2000)	Control Of A Sterilization Process For Medical Devices

Attachment B of Declaration of conformity - Standards List

Title: Declaration of Conformity

Doc. No.: CE00004-01 Ver.: A/7 Page 3 of 4

	- 	
	2015	Sterilization Of Health Care Products-Radiation-Part
(ISO 11137-2)	(2013)	2:Establishing The Sterilization Dose
EN ISO 11737-1	1019	Sterilization of health care products. Microbiological methods.
		Part 1:Determination of a population of microorganisms on
(150 11/5/-1)		products
EN ISO 11737-2	2000	Sterilization of medical devices - Microbiological methods -
		Part 2: Tests of sterility performed in the definition, validation
(150 11757-2)	(=013)	and maintenance of a sterilization process
EN ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1:
(ISO 14644-1)	(2015)	Classification of air cleanliness by particle concentration
EN ISO 14644 2	2016	Cleanrooms and associated controlled environments - Part 2:
		Monitoring to provide evidence of cleanroom performance
(150 14044-2)	(2015)	related to air cleanliness by particle concentration
EN ISO 5832-2	2018	Implants for surgery. Metallic materials. Part 2:Unalloyed
(ISO 5832-2)	(2018)	titanium
EN ISO 14630	2012	
(ISO 14630)	(2012)	Non-active surgical implants General requirements
ASTM D4169	2016	Standard Practice for Performance Testing of Shipping
		Containers and Systems
IEC 62366 1	2015	Medical devices - Part 1: Application of usability
	2015	engineering to medical devices
EN ISO 11135	2014	Sterilization of health-care products - Ethylene oxide -
		Requirements for the development, validation and routine
(100 11100)	(2014)	control of a sterilization process for medical devices
	(ISO 14644-1) EN ISO 14644-2 (ISO 14644-2) EN ISO 5832-2 (ISO 5832-2) EN ISO 14630 (ISO 14630)	(ISO 11137-2)(2013)EN ISO 11737-1 (ISO 11737-1)2018 (2018)EN ISO 11737-2 (ISO 11737-2)2009 (2019)EN ISO 14644-1 (ISO 14644-1)2015 (2015)EN ISO 14644-2 (ISO 14644-2)2015 (2015)EN ISO 14644-2 (ISO 14644-2)2015 (2015)EN ISO 5832-2 (ISO 14630)2012 (2012)EN ISO 14630 (ISO 14630)2012 (2012)ASTM D41692016IEC 62366-1 EN ISO 111352014

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, Ridlerstraße. 65, 80339 München, Germany

Identification Number: 0123

Signature of issuing person:

Certificate No: G2S 18 04 91657 012

Date of CE mark was affixed:July.29th, 2013Expiration date of CE certificate:July. 28th, 2023

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

Title: Declaration of Conformity Ver.: A/6 Doc. No.: FRKM/CE 05-01 Page 1 of 4

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

Title: Declaration of Conformity Ver.: A/6 Doc. No.: FRKM/CE 05-01 Page 2 of 4

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	2018 (2017)	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
8	(ISO 10993-11) 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

Title: Declaration of Conformity Ver.: A/6 Doc. No.: FRKM/CE 05-01 Page 3 of 4

SUZHOU FRANKENMAN MEDICAL EQUIPMENT CO., LTD.

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 2:
	(ISO 11137-2)	(2013)	Establishing the sterilization dose
17	EN ISO 11737-1	2018	Sterilization of Medical Device-Microorganisms Method-
	(ISO 11737-1)	(2018)	Part 1 Determination of the Microorganisms on Products
18	EN ISO 11737-2	2009	Sterilization of Medical Device- Microorganisms Method-
	(ISO 11737-2)	(2019)	Part 2: Asepsis Test carried out during sterilization
19	EN ISO 14644-1	2015	Cleanrooms and associated controlled environments Part
	(ISO 14644-1)	(2015)	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



(Manufac	N OF CONFORMITY cturer's Declaration) h record of final inspection for a specific lot./device enclosed.
MANUFACTURER	dalim SurgNET CorporationB-708, 1002 Woolim Blue nine, 583, Yangcheon-ro, Gangseo-gu, Seoul 07547, KoreaTelephone+82 2 2093 7888Fax+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:	Па
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 House Noorderlaan 87 2030 Antwerp Belgium

START OF CE-MARKING PLACE, DATE OF ISSUE:

SIGNATURE:

In Seoul, 2010-12-27



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)	lla	7	Annex II excluding section 4	14155	2010-12-27
2	TRANSPORT (TR05FL)	lla	7	Annex II excluding section 4	14155	2010-12-27
3	TRANSPORT (TR05FL110)	lla	7	Annex II excluding section 4	14155	2012-01-16
4	TRANSPORT (TR03)	lla	7	Annex II excluding section 4	14155	2013-05-02
5	TRANSPORT (Tport05)	lla	7	Annex II excluding section 4	14155	2013-05-02
6	TRANSPORT (Tport10)	lla	7	Annex II excluding section 4	14155	2015-08-10
7	TRANSPORT (Tport12)	lla	7	Annex II excluding section 4	14155	2015-08-10
8	TRANSPORT (TR10F)	lla	7	Annex II excluding section 4	14155	2013-05-02
9	TRANSPORT (TR10FL)	lla	7	Annex II excluding section 4	14155	2015-08-10
10	TRANSPORT (TR10FL150)	lla	7	Annex II excluding section 4	14155	2015-08-10
11	TRANSPORT (TR12F)	lla	7	Annex II excluding section 4	14155	2013-05-02
12	TRANSPORT (TR12FL)	lla	7	Annex II excluding section 4	14155	2015-08-10
13	TRANSPORT (TR12FL150)	lla	7	Annex II excluding section 4	14155	2015-08-10
14	TRANSPORT (TR03C)	lla	7	Annex II excluding section 4	14155	2015-08-10
15	TRANSPORT (TR05FC)	lla	7	Annex II excluding section 4	14155	2015-08-10
16	TRANSPORT (TR05FLC)	lla	7	Annex II excluding section 4	14155	2015-08-10
17	TRANSPORT (TR05FL110C)	lla	7	Annex II excluding section 4	14155	2015-08-10

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



<u>Attachment 2.</u>

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



(Manufac	N OF CONFORMITY cturer's Declaration) h record of final inspection for a specific lot./device enclosed.
MANUFACTURER	dalim SurgNET CorporationB-708, 1002, Woolim Blue nine, 583, Yangcheon-ro, Gangseo-gu, Seoul 07547, KoreaTelephone+82 2 2093 7888Fax+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:	Па
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:

NOTIFIED BODY (EC) CERTIFICATE(S):

START OF CE-MARKING PLACE, DATE OF ISSUE: Refer to the attachment #2.

SGS SGS House Noorderlaan 87 2030 Antwerp Belgium

In Seoul, 2009-09-15



SIGNATURE:

President

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: OCTOTM

EC-CERTIFICATE No.: KR19/81826219

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

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

/ Approved by Yuanchao Wang

Prepared by Yiseul Kang __________ cf. Notified Body is SGS, identification no. 1639

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







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.: Valid from: Valid until: SH2008702 2021-04-26 2023-06-11

Christoph Dicks Head of Certification/Notified Body

Date, 2021-04-26





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, PEOPLE'S REPUBLIC OF CHINA

Suzhou Frankenman Medical Equipment Co., Ltd.

108 South Jinfeng Road, Suzhou High-New District, 215163

See Scope of Certificate







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

Page 1 of 1 Date of Issue: 2020-08-07

Tina Israel Manager, US Certification Body, Medical and Health Services TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com