

**Product List und Application
MDD, AIMDD**



Name Legal
Manufacturer

Changzhou City Zhiye Medical Devices Institute

Address Legal
Manufacturer

No. 127, Xiacheng Road, Mahang, Changzhou, 213162 Jiangsu, China

MDD 93/42/EEC

Annex II excluding Section 4

Reason for
submission of
product list

Add new product(s)

Reference

Changzhou City Zhiye Medical Devices Institute / 2019-12-30

Product List und Application MDD, AIMDD



Declaration of the applicant

I hereby apply for the assessment of my quality assurance system with respect to the product(s) listed hereafter.

I hereby declare

- that no application has been lodged with any other notified body for the same product-related quality system.

In relation to the quality assurance system I assure

- to fulfil the obligations imposed by the quality system approved;
- to keep the approved quality system adequate and efficacious;
- to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action;
- to notify the competent authorities and TÜV Rheinland LGA Products GmbH of the following incidents immediately on learning of them:
 - i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
 - ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph i) to systematic recall of devices of the same type by the manufacturer.

Additionally I declare

- to submit to the notified body the relevant documentation on the quality assurance system and the necessary documentation on the product(s) to be evaluated ("technical documentation");
- to keep the relevant documentation including documents provided by TÜV Rheinland LGA Products GmbH for a duration of at least five years, and, in the case of implantable devices at least 15 years, after manufacture of the last product;
- that all listed devices meet the essential requirements set out in Annex I of Directive 93/42/EEC;
- to inform TÜV Rheinland LGA Products GmbH without delay in case of inquiries by any competent authority regarding the products covered by this application;
- to inform TÜV Rheinland LGA Products GmbH about any planned substantial changes to the approved quality assurance system (e. g. procedural changes regarding design and development, production, or end control), or the products/product range covered by it;
- to submit an informal application for certificate extension to the notified body, at least 6 months before expiry of the certificate. A different date may be agreed by means of a contract:

TÜV Rheinland LGA Products GmbH
Certification Office Medical
Am Grauen Stein 29
51105 Cologne
Germany
E-Mail: medical-products@de.tuv.com

As a manufacturer who does not have a registered place of business in an EU member state, (including states holding an appropriate agreement with the EC), I additionally declare,

- to designate per product one authorized representative established in the Community;
- to inform TÜV Rheinland LGA Products GmbH in case the authorized representative has changed;
- that the authorized representative keeps all relevant product documentation, including the declaration of conformity, for a duration of at least five years, and in the case of implantable devices at least 15 years, after manufacture of the last product;
- to sign an agreement with the authorized representative which clearly defines the interfaces and responsibilities, in order to comply with the current "EC Guidelines on a Medical Devices Vigilance System".

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Code of facilities	Scope of facilities	Name of facility	Address of facility	
EAR(1)	European Authorized Representative	Stapleline Medizintechnik GmbH	Bessemmer, Str 30,44793, Bochum, Germany Tel: 0049-0234/936487-00 DIMDI No.: DE/0000043336	
IMF(1)	Internal Manufacturing Facility	Changzhou City Zhiye Medical Devices Institute	No. 127, Xiacheng Road, Mahang, Changzhou, 213162 Jiangsu, China	
EMF(1)	External Manufacturing Facility			
R&D(1)	Research & Development	Changzhou City Zhiye Medical Devices Institute	No. 127, Xiacheng Road, Mahang, Changzhou, 213162 Jiangsu, China	
OEM(1)	Original Equipment Manufacturer			
Sterilization facility Radiation (1)				

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MS-0023786

Revision: 0

Effective date: 15-Aug-2017

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TÜVRheinland®

Sterilization facility Gas(1)	Ethylene oxide	Changzhou City Zhiye Medical Devices Institute	No. 127, Xiacheng Road, Mahang, Changzhou, 213162 Jiangsu, China
Sterilization facility Heat(1)			
Sterilization facility: Other sterilization methods(1)			

TÜV Rheinland®

add a new product		delete the last product	add a copy of the last line		table reset						
Product name (as listed on label)	General product group name	Classification Rule including subclause according to Annex IX	Device Class	Allocation of all products into Device Subcategories [NBOG BPG 2009-3]	Allocation of class IIb products into Generic Device Groups	GMDN number for class IIb products only	TD/DD identifier	Choose from above code of facilities	Summary list of related facilities	Code of EU-REP [see above]	
Disposable Endoscopic Ligating Loops TZ-300	Disposable Endoscopic Ligating Loops	rule 8.2.4.1	IIb	MD 0302 Sutu	Endotherapy Ligature Loop, single-use	17785	CE20		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)	
Dilators 5,7,9,11,13,15	Dilators	rule 6.2.2.1	IIa	MD 0106 Non-	N/A	N/A	CE03		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)	
Disposable Haemorrhoidal Cutter Staplers and Accessories model: GH-Y32/34/36, PAH32-TF, PAH34-TF, PAH36-TF, PAH32-TF-ST, PAH34-TF-ST, PAH36--TF-ST	Disposable Haemorrhoidal Cutter Staplers and Accessories	rule 8, 2.4.1	IIb	MD 0302 Sutu	Haemorrhoidal surgical stapler, single-use	46737	CE02		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)	
Biopsy Forceps HQ1.8, HQ2.3	Biopsy Forceps	rule 6, 2.2.1	IIa	MD 0106 Non-	N/A	N/A	CE06		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)	

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Hernia Patches SB-A SB-B, SB-C	Hernia Patches	rule 8, 2.4.1	IIb	MD 0204 Non-	Abdominal hernia surgical mesh, synthetic polymer	60300	CE05		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Skin Staplers and Removers PH-W, PH-R	Skin Staplers and Removers	rule 6, 2.2.1	IIa	MD 0302 Sutu	N/A	N/A	CE07		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Disposable Endoscopic Scissors JD330, JD430	Disposable Endoscopic Scissors	rule 6, 2.2.1	IIa	MD 0106 Non-	N/A	N/A	CE08		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Disposable Endoscopic Dissectors FQ330, FQ430	Disposable Endoscopic Dissectors	rule 6, 2.2.1	IIa	MD 0106 Non-	N/A	N/A	CE10		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Disposable Endoscopic Graspers ZQ330, ZQ430	Disposable Endoscopic Graspers	rule 6, 2.2.1	IIa	MD 0106 Non-	N/A	N/A	CE09		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Disposable Endoscopic Retrieval Bag QW1, QW2, QW3, QW4, QW5	Disposable Endoscopic Retrieval Bags	rule 6, 2.2.1	IIa	MD 0106 Non-	N/A	N/A	CE11		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)

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Disposable Clip Appliers TQ5, TQ10	Disposable Clip Appliers	rule 8, 2.4.1	IIb	MD 0302 Sutur	Laparoscopic clip applier	58040	CE14		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Disposable Trocars CCQ-Y, CCQ-W	Disposable Trocars	rule 6, 2.2.1	IIa	MD 0106 Non-	N/A	N/A	CE13		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Disposable Suction and Irrigation Tubes CX330, CX430	Disposable Suction and Irrigation Tubes	rule 6, 2.2.1	IIa	MD 0106 Non-	N/A	N/A	CE12		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Disposable Veress Needles QF-120, QF-150	Disposable Veress Needles	rule 6, 2.2.1	IIa	MD 0106 Non-	N/A	N/A	CE15		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Hernia Staplers LW-350, LW-110	Hernia Staplers	rule 8, 2.4.1	IIb	MD 0302 Sutur	Surgical mesh laparoscopic delivery/ positioning device	61372	CE19		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Purse Strings Staplers YHB-45, YHB-65	Purse Strings Staplers	rule 6, 2.2.1	IIa	MD 0302 Sutur	N/A	N/A	CE16		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)

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Reusable Surgical Staplers DW-25, DW-27, DW-29, DW-32, DG-32, DG-34, DG-36, DF-30, DF-45, DF-60, DF-75, DF-90	Reusable Surgical Staplers	rule 8, 2.4.1	IIb	MD 0302 Sutu	Manual surgical stapler, reusable	32369	CE17		IMF(1);R&D(1);	EAR(1)
Duodenal stent Model: see attachment.	Non-vascular Stents	rule 8, 2.4.1	IIb	MD 0204 Non-	Duodenal stent	32640	CE01		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Bare-metal biliary stent Model: see attachment.	Non-vascular Stents	rule 8, 2.4.1	IIb	MD 0204 Non-	Bare-metal biliary stent	43691	CE01		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Bare-metal bronchial stent Model: see attachment.	Non-vascular Stents	rule 8, 2.4.1	IIb	MD 0204 Non-	Bare-metal bronchial stent	43589	CE01		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Bare-metal colonic stent Model: see attachment.	Non-vascular Stents	rule 8, 2.4.1	IIb	MD 0204 Non-	Bare-metal colonic stent	37847	CE01		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)

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Bare-metal oesophageal stent Model: see attachment.	Non-vascular Stents	rule 8, 2.4.1	IIb	MD 0204 Non-	Bare-metal oesophageal stent	43573	CE01		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Bare-metal ureteral stent Model: see attachment.	Non-vascular Stents	rule 8, 2.4.1	IIb	MD 0204 Non-	Bare-metal ureteral stent	58004	CE01		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Duodonal Colonic Stent Type: NTJ-B- φ18/20/22/25/28/30x 60/80/100-Q/L	Non-vascular Stents	rule 8, 2.4.1	IIb	MD 0204 Non-	Polymer-metal duodenal stent (en)	62039	CE0103		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Polymer-metal Biliary stent Type: NTJ-B- φ6/8/10x30/40/50/60 /70/80/90/100	Non-vascular Stents	rule 8, 2.4.1	IIb	MD 0204 Non-	Polymer-metal biliary stent (en)	43566	CE0108		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Polymer-metal tracheal stent Type: NTJ- φ10/11/12/13/14/15/ 16/17/18x30/35/40/4 5/50/55/60/65/70/80/ 90	Non-vascular Stents	rule 8, 2.4.1	IIb	MD 0204 Non-	Polymer-metal tracheal/ bronchial stent, sterile (en)	43630	CE0106		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)

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Polymer-metal colonic stent Type: NTJ-B- φ18/20/22/25/28/30x 60/80/100-Q/L	Non-vascular Stents	rule 8, 2.4.1	IIb	MD 0204 Non-	Polymer-metal colonic stent (en)	62040	CE0105		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Memory Ni-Ti Alloy Esophagus Stent Type: NTJ-B/D- φ12/14/16/18/20x (30-160)	Non-vascular Stents	rule 8, 2.4.1	IIb	MD 0204 Non-	Polymer-metal oesophageal stent, sterile (en)	61751	CE0104		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Polymer-metal urethral stent Type: NTJ- φ13/14x25/30/35/40/ 45/50	Non-vascular Stents	rule 8, 2.4.1	IIb	MD 0204 Non-	Polymer-metal urethral stent (en)	42698	CE0107		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)

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Disposable Linear Staplers and Cartridges Type: ZFB/ZFH30(45/60/90), SZH-30 (45/60/90)-2/3/4 FH-Y-30 (45/60/90)-3.8/4.5 Reloads models: ZCB/ZCH30(45/60/90) SCB/SCH-30 (45/60/90)-2.5/3.8/4.5 CLB/CLG30 (45/60/90)-3.8/4.5	Disposable Linear Staplers and Cartridges	rule 8, 2.4.1	IIb	MD 0302 Sutu	Open-surgery manual linear stapler, single- use	59873	CE0204		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)

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Disposable Circular Staplers models: WH-Y- (14/17/19/21/24/26/2 9/32/34), WH-Y-T (21,24/26/29/32/34) ZQH (14/17/19/21/24/25/2 6/27/29/31/32/33/34), SWH-Y- (14/17/19/21/24/26/2 9/32/34)	Disposable Circular Staplers	rule 8, 2.4.1	IIb	MD 0302 Sutu	Intraluminal circular stapler, single-use	59875	CE0201		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)

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Disposable Linear Cutting Staplers and Cartridges Type: Stapler models: QHB/QHH55 (75/100)-3.8/4.5 QGB/QGH60 (80/100)-3.8/4.5 Reload models: QCB/QCH55 (75/100)-3.8/4.5 QGC/ QGCH60 (80/100)-3.8/4.5	Disposable Linear Cutting Staplers and Cartridges	rule 8, 2.4.1	IIb	MD 0302 Sutu	Open-surgery manual linear cutting stapler, single-use	59870	CE0203		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)
Disposable Curved Cutter Staplers Type: HX-45	Disposable Curved Cutter Staplers	rule 8, 2.4.1	IIb	MD 0302 Sutu	Open-surgery manual linear cutting stapler, single-use	59870	CE0208		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)

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Disposable Endoscopic Linear Cutting Staplers and Cartridges Type: Stapler models: ZNQ-(A/B/C) ZNQIIA/B, Reload models: ZN-Z-30/45/60- (2.0/2.5/3.5/4.0/4.8), ZN-30/45/60 (2.0/2.5/3.5/4.0/4.8), ZNUJIZ/ D-30/45/60-1/2/3	Disposable Endoscopic Linear Cutting Staplers and Cartridges	rule 8, 2.4.1	IIb	MD 0302 Sutu	Endoscopic manual linear cutting stapler, single-use	59871	CE28		IMF(1);R&D(1); Sterilization facility Gas(1);	EAR(1)

Date

30.12.2019

Location

Changzhou

Legally binding
signature

Reference

Changzhou City Zhiye Medical Devices Institute / 2019-12-30

MS-0023786

Revision: 0

Effective date: 15-Aug-2017

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