1 z 1

mgr Katarzyna Przybyś-Preiskorn
Tłumaczka przysięgła języka angielskiego
przy Ministerstwie Sprawiedliwości
Nr TP/883/05
05-410 Józefów, Spacerowa 43b
tel/fax (+22) 789 29 37
[tłumaczenie z jęz. angielskiego]

Business Stream Products *[logo TUV Rheinland]*

Dział certyfikacji TÜV Rheinland LGA Products GmbH □ 51105 Köln

Grena (Qingdao) Medical Devices Ltd.
No.318 Huanghe West Road, Huangdao District,
Qingdao City, 266555 Shandong,
Republika Chińskiej Republiki Ludowej

Kontakt
Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com
Data 23 kwietnia 2023 r.

Do wszystkich zainteresowanych,
TÜV Rheinland LGA Wyroby GmbH jednostka notyfikowana 0197 potwierdza, że certyfikat oparty na MDD 93/42/EWG, załącznik II z wyłączeniem (4) certyfikat nr. HD 60128685 0001 i na MDD 93/42/EWG, załącznik V nr. DD 60128686 0001 producenta Grena (Qingdao) Medical Devices Ltd. nie podlegał żadnym ograniczeniom lub warunkom, takim jak zawieszenie lub wycofanie w dniu wygaśnięcia.
Producent Grena (Qingdao) Medical Devices Ltd. złożył wniosek o ocenę zgodności na podstawie MDR (UE) 2017/745 załącznik IX rozdział I.
Wyroby objęte wnioskiem są wymienione w załączonym Wykazie wyrobów i Wniosku z dnia 2023-04-19.
Z wyrazami szacunku,
Fuxiu Sheng
Jednostka certyfikująca
Załącznik: Lista wyrobów i Wniosek

[w kolumnie po prawej stronie dane teleadresowe oraz biznesowe TÜV Rheinland LGA Products GmbH

POŚWIADCZAM, ŻE POWYŻSZE TŁUMACZENIE JEST ZGODNE Z PRZEDSTAWIONYM MI ..... DOKUMENTU
mgr KATARZYNA PRZYBYŚ-PREISKORN
TŁUMACZ PRZYSIĘGŁY JĘZYKA ANGIELSKIEGO
JÓZEFÓW, DN. 24.08.2023 Nr REPERTORIUM 2413/08123

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Grena (Qingdao) Medical Devices Ltd.
No.318 Huanghe West Road, Huangdao District,
Qingdao City, 266555 Shandong,
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date April 23, 2023

To Whom it may concern,

TÜV Rheinland LGA Products GmbH the notified body 0197 confirms that the certificate based on MDD 93/42/EEC, Annex II excluding (4) certificate no. HD 60128685 0001 and MDD 93/42/EEC, Annex V certificate no. DD 60128686 0001 of the manufacturer Grena (Qingdao) Medical Devices Ltd. was not subject to any restrictions or conditions, such as suspension or withdrawal at the date of expiry.

The manufacturer Grena (Qingdao) Medical Devices Ltd. has lodged an application for conformity assessment based on MDR (EU) 2017/745 annex IX chapter I.

Products covered by the application are listed in the attached Product List and Application dated 2023-04-19.

Best regards,

Fuxiu Sheng

Certification body

Attachment:
Product List and Application

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Product List and Application MDR QM part	TÜVRheinland®

Name of Legal Manufacturer (shall be identical as given in General Agreement with TRLP):	Grena (Qingdao) Medical Devices Ltd.
Additional registered trade name or registered trade mark of the manufacturer (used on the label; MDR Annex I clause 23.2.c):	GRENA®
Address of Legal Manufacturer:	No.318 Huanghe West Road, Huangdao District. Qingdao City, 266555 Shandong, China
EUDAMED Single Registration No:	CN-MF-000009861
MDR (EU) 2017/745:	Annex IX Chapter I, Section 2 and 3
Reason for submission:	New product list

☐ **This Product List and Application replaces all previous applications.** In case of changes to a previous version of the Product List and Application, please mark all changes in red font color and in **bold.** In case of deleting products from the portfolio, please cross out the relevant products.

☐ **This Product List and Application is an addendum to the initial application** dated YYYY-MM-DD. (Please only list the added products)

Please provide a legally binding signed version of this document by fax, 2-fold by post (**note: not all data will be printed**) **or electronically signed (advanced or qualified signature according to eIDAS Regulation (EU) No 910/2014). In addition please provide this Product List and Application as as Excel file.**

Declaration of the applicant
I hereby apply for the assessment of my quality management/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 device-related quality system.

In relation to the quality assurance system I assure
- to fulfil the obligations imposed by the Medical Device Regulation 2017/745 on establishing, documenting, implementing and maintaining a quality management system;
- to keep the approved quality system adequate and efficacious;
- to institute and keep up to date a system to review experience gained from post-market surveillance, including the provisions referred to in Annex III, and to inform the notified body about initiated corrective and / or preventive actions;
- to notify the competent authorities and TÜV Rheinland LGA Products GmbH of the following as described in accordance with Article 87:
  a) any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;
  b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country. The reports referred to in the first subparagraph shall be submitted through the electronic system referred to in Article 92.
- to notify the competent authorities and TÜV Rheinland LGA Products GmbH of the following as described in accordance with Article 88:
  Any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.

For applications according to Annex XI Part A

Additionally I declare:

- **that I have not withdrawn an application with another notified body prior to the decision of that notified body, OR**
- **that I provide all information about any previous application with another notified body prior to the decision of that notified body for the same conformity assessment that has been withdrawn, including information about the refusal by that other notified body, as applicable**

- to submit to the notified body the relevant documentation as defined in Annex IX, Chapter, I Section 2.1;
- to keep the relevant documentation including documents provided by TÜV Rheinland LGA Products GmbH for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market in order to fulfil Chapter II Article 10 Par. 8
- that all listed devices meet the general safety and performance requirements set out in Annex I;
- that used registered trade name(s) and/or registered trade mark(s) of the manufacturer used in accordance with MDR 2017/745, Annex I, 23.2 (c) are not separate legal persons.
- 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 management system (e. g. procedural changes regarding design and development, production, or end control), or the products/product range covered by it, and not to implement such substantial changes prior to a notification from TÜV Rheinland LGA Products GmbH to do so.
  Note: For guidance on substantial change notification refer to NBOG best practice guide 2014-3;
- to submit an informal application for certificate re-assessment 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
E-mail for vigilance cases: medical-vigilance@tuv.com

In case of an application for a conformity assessment procedure according to Annex XI Part A (Production quality assurance) the manufacturer shall attach a copy of the EU type-examination certificate referred to in Section 4 of Annex X and relevant notified body examination reports, as applicable.

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 generic device group one authorised representative established in the Community;
- that the designation is accepted in writing by the authorised representative
- to inform TÜV Rheinland LGA Products GmbH in case the authorised representative has changed;
- that the authorised representative has permanently available and keeps the relevant documentation including documents provided by TÜV Rheinland LGA Products GmbH to allow the authorised representative to fulfil the tasks mentioned in Article 11(3) for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.
- to sign an agreement with the authorised representative which enables the authorised representative to fulfil the delegated tasks as defined in Article 11(3).

Product List and Application MDR QM part	TÜVRheinland®

FACILITIES:

Code of facility	Scope of facility	Legal entity name of facility	Address of facility
EAR(1)	European authorised Representative	MDML INTL Limited	10 McCurtain Hill Clonakilty, Co. Cork Republic of Ireland
IMF(1)	Internal Manufacturing Facility	Grena (Qingcao) Medical Devices Ltd.	No.318 Huanghe West Road, Huangdao District, Qingdao City, 266555 Shandong, China
EMF(1)	External Manufacturing Facility		
IR&D(1)	Internal Research & Development	Grena (Qingdao) Medical Devices Ltd.	No.318 Huanghe West Road, Huangdao District, Qingdao City, 266555 Shandong, China
ER&D(1)	External Research & Development		
S_RAD(1)	Sterilization facility Radiation : Electron beam	[redacted]	
S_GAS(1)	Sterilization facility Gas : Ethylene oxide	Grena (Qingdao) Medical Devices Ltd.	No.318 Huanghe West Road, Huangdao District, Qingdao City, 266555 Shandong, China
S_HEAT(1)	Sterilization facility Heat - Please select method		
S_OTH(1)	Sterilizaton facility Other : Please specify		

Please add lines as required!

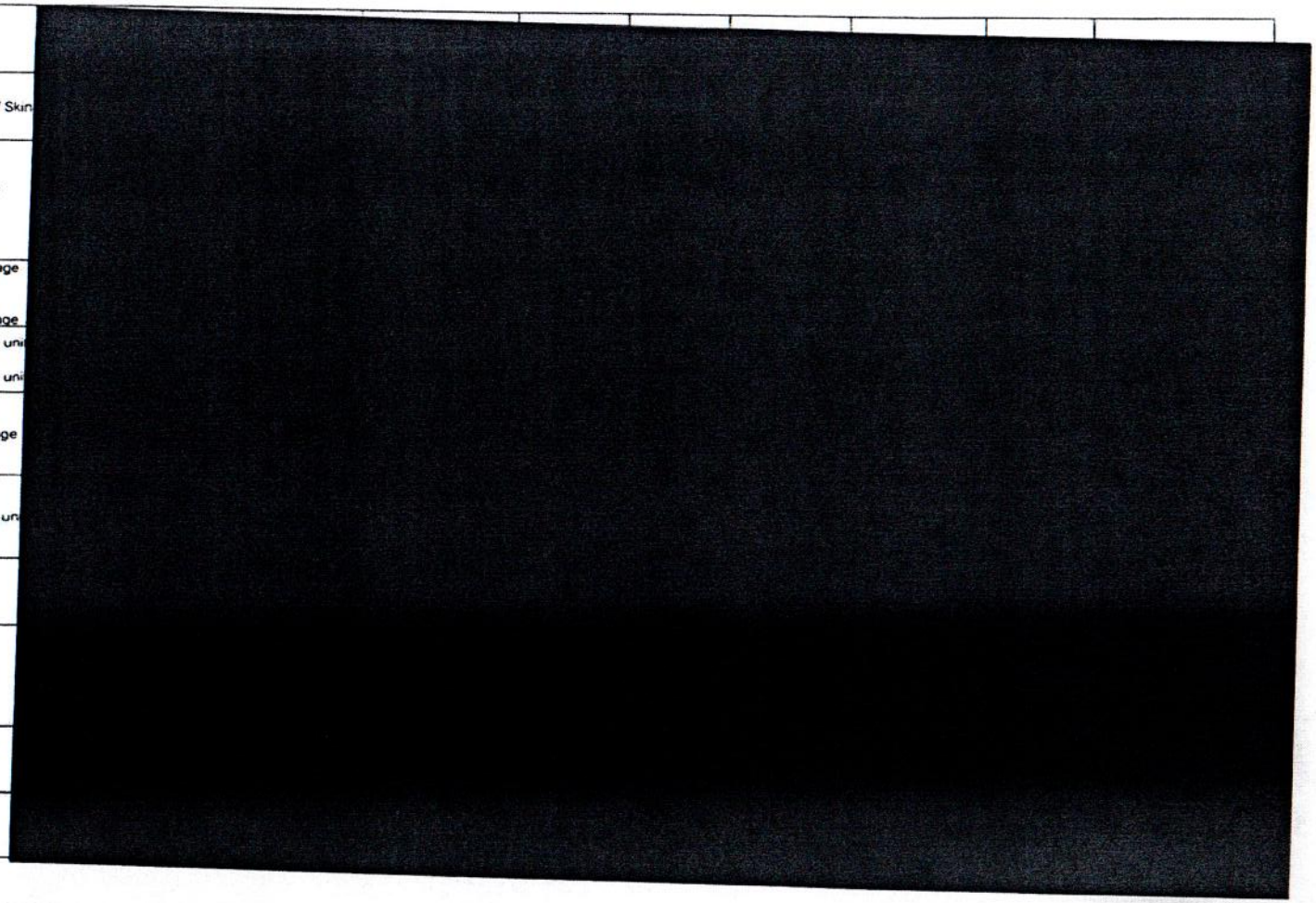
Note: To add line, please select and copy entire corresponding row, insert copied row and adapt the numbers in brackets (e.g. S_RAD (1), S_RAD (2),

PRODUCTS:

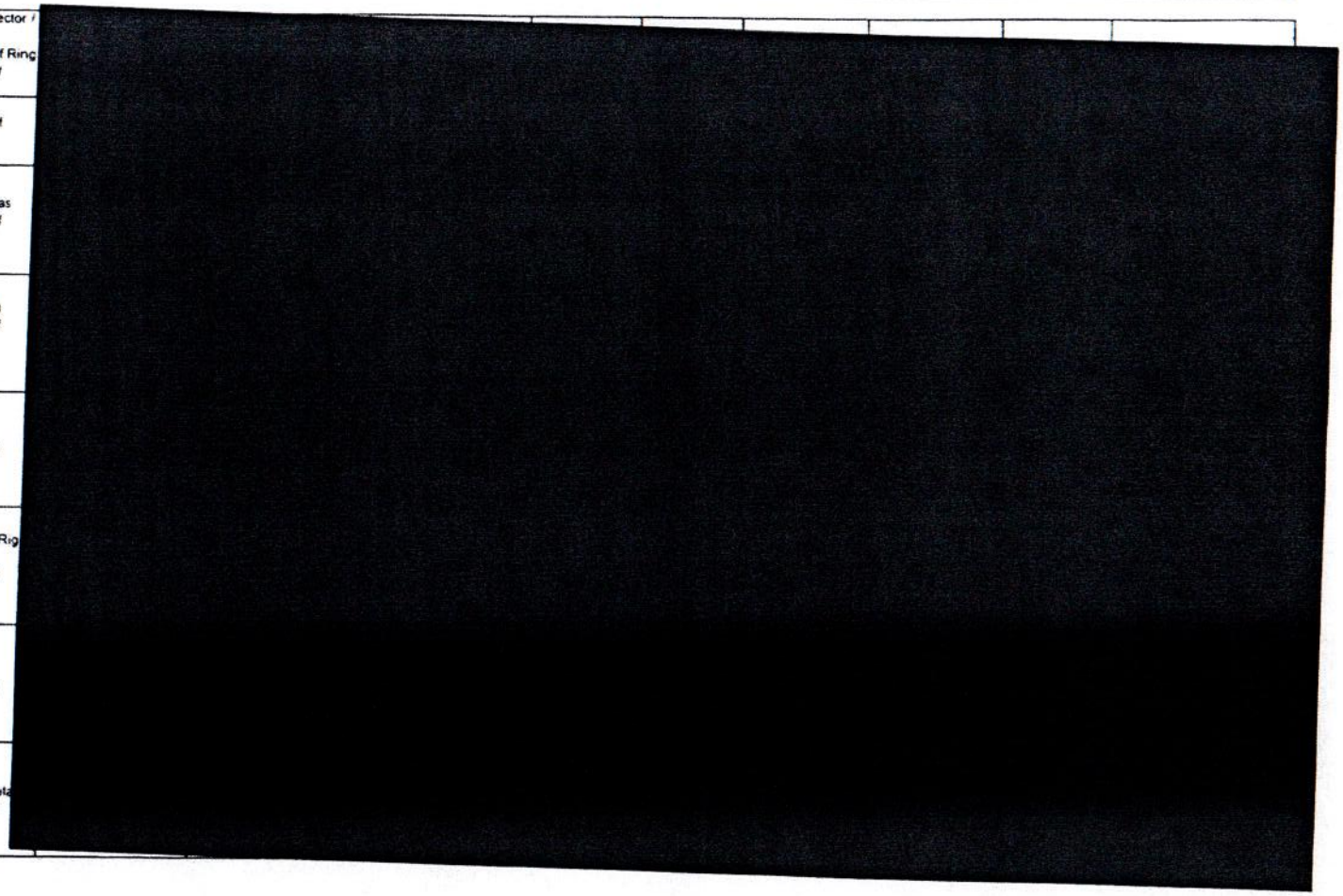
Note: Please provide an information for all columns (also the blue columns which will not be printed).

No	Product name or Trade Name (as listed on label)
1	LigaV® Ligating Clip Applier,open surgery Model No. see ATTACHMENT 1-List of LigaV® Ligating Clip Applier,open surgery
2	LigaV® Ligating Clip Applier,endoscopic Model No. see ATTACHMENT 2-List of LigaV® Ligating Clip Applier,endoscopic
3	Vclip® Ligating Clip Applier, open surgery Model No. see ATTACHMENT 3-List of Vclip® Ligating Clip Applier,open surgery
4	Vclip® Ligating Clip Applier, endoscopic Model No. see ATTACHMENT 4-List of Vclip® Ligating Clip Applier,endoscopic
5	Click'aV® Ligating Clip Applier,open surgery Model No. see ATTACHMENT 5-List of Click'aV® Ligating Clip Applier,open surgery
6	Click'aV® Ligating Clip Applier,endoscopic Model No. see ATTACHMENT 6-List of Click'aV® Ligating Clip Applier,endoscopic
7	Click'aV® Ligating Clip Remover,open surgery Model No. see ATTACHMENT 7-List of Click'aV® Ligating Clip Remover,open
8	Click'aV® Ligating Clip Remover,endoscopi Model No. see ATTACHMENT 8-List of Click'aV® Ligating Clip Remover,endoscop

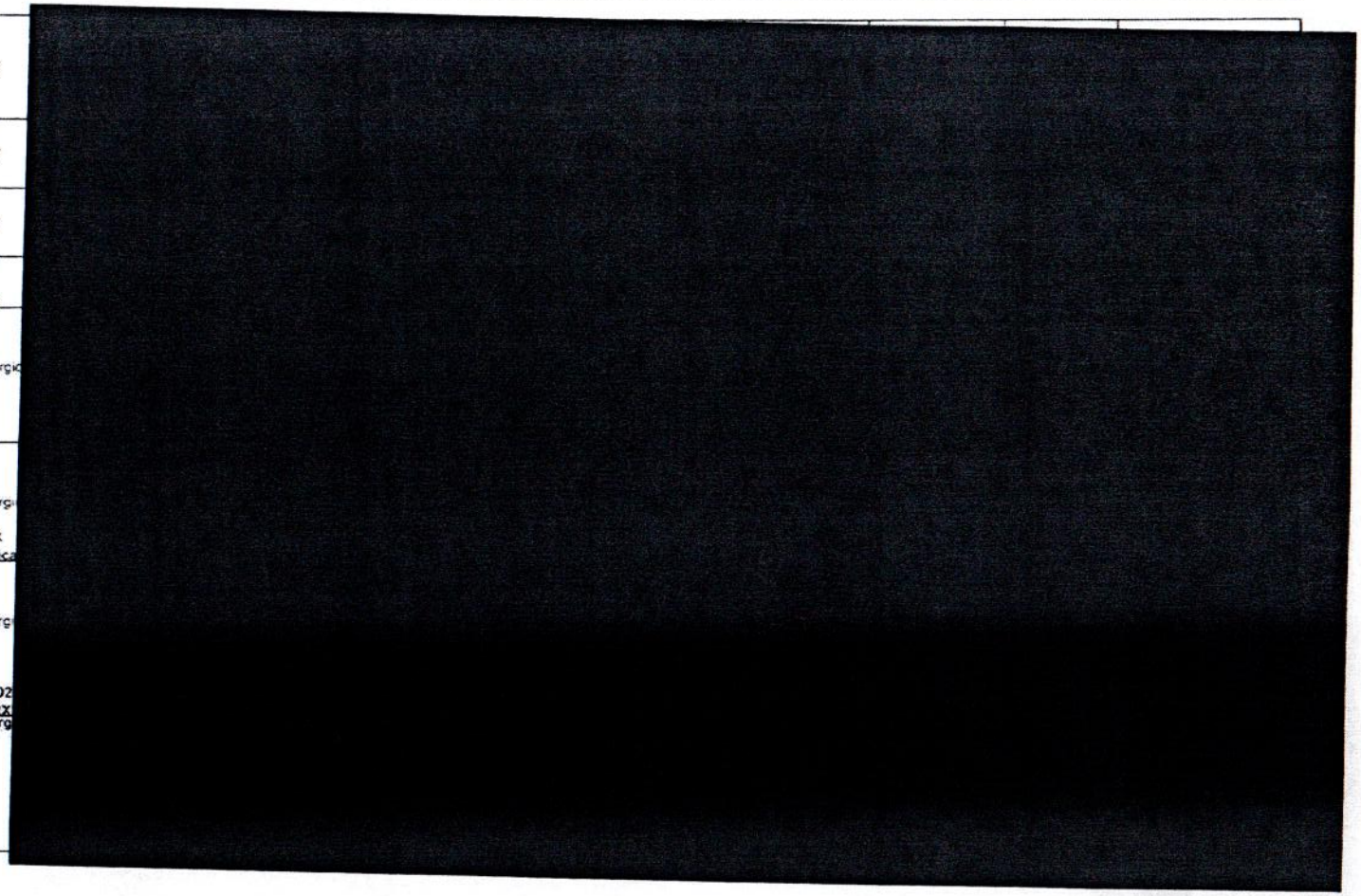
9	Connecting tube Model No. see ATTACHMENT 9-List of Connecting tube
10	Skin staple remover Model No. see ATTACHMENT 10-List of Skin staple remover
11	Tubing set for chest drainage unit Model No. see ATTACHMENT 11-List of Tubing set for chest drainage unit
12	Disposable plastic bottle for Chest drainage unit Model No. see ATTACHMENT 12-List of Disposable plastic bottle for Chest drainage
13	Reusable glass bottle for Chest drainage uni Model No. see ATTACHMENT 13-List of Reusable glass bottle for Chest drainage uni
14	Chest drainage unit (Plastic bottle) incl. Tubing set for chest drainage unit & Disposable plastic bottle for Chest drainage unit Model No. see ATTACHMENT 14-List of
15	Chest drainage unit (Glass bottle) incl. Tubing set for chest drainage unit & Reusable glass bottle for Chest drainage uni Model No. see ATTACHMENT 15-List of Chest
16	Reusable Trocar Model No. see ATTACHMENT 16-List of Reusable Trocar
17	Disposable skin stapler Model No. see ATTACHMENT 17-List of Disposable skin stapler
18	Veress Needle Model No. see ATTACHMENT 18-List of Veress Needle
19	Retrieval Bag Model No. see ATTACHMENT 19-List of Retrieval Bag



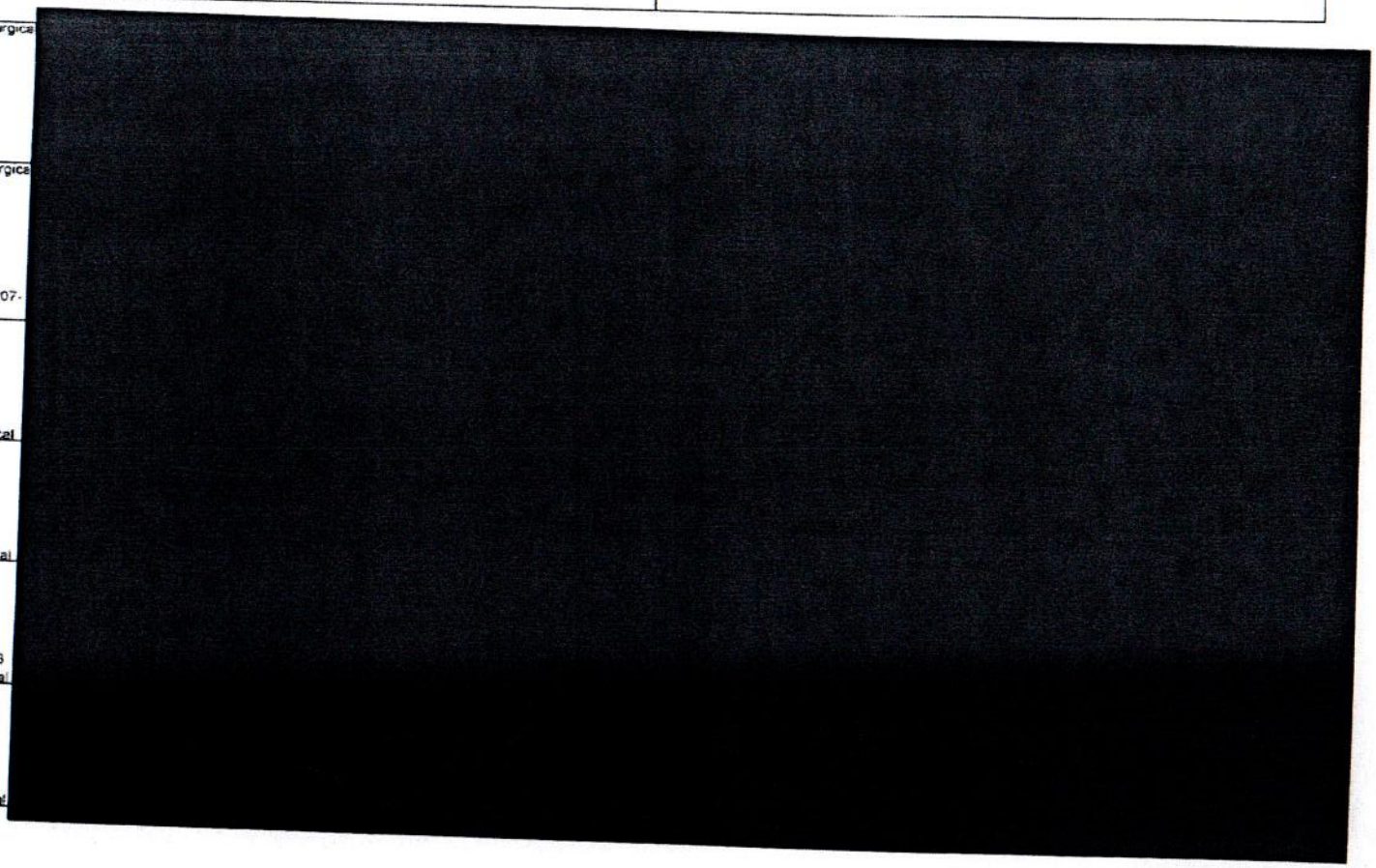
20	Ring Protect™ Disposable Wound Protector / Retractor Model No. see ATTACHMENT 20-List of Ring Protect™ Disposable Wound Protector / Retractor
21	Silicone Sling Model No. see ATTACHMENT 21-List of Silicone Sling
22	Suction-irrigation Set, parts including Suction-irrigation cannulas Model No. see ATTACHMENT 22-List of Suction-irrigation Set
23	Suction-irrigation Set (Economy version) Model No. see ATTACHMENT 23-List of Suction-irrigation Set (economy version)
24	Endoscopic suction set Model No. see ATTACHMENT 24-List of Endoscopic suction set
25	Suction Set (Rigid, Rigid bulb), parts including Suction cannulas (Rigid, Rig bulb) Model No. see ATTACHMENT 25-List of Suction Set (Rigid, Rigid bulb)
26	Suction Set (Mini, Standard), parts including Suction cannulas (Mini, Standard) Model No. see ATTACHMENT 26-List of Suction Set (Mini, Standard)
27	Orthopaedic Suction Set, part including Orthopaedic Suction cannula Model No. see ATTACHMENT 27-List of Orthopaedic Suction Set



28	Thoracentesis/Paracentesis Set Model No. see ATTACHMENT 28-List of Thoracentesis Paracentesis Set
29	Titanium Ligating Clips Model No. see ATTACHMENT 29-List of Titanium Ligating Clips
30	Polymer Ligating Clips Model No. see ATTACHMENT 30-List of Polymer Ligating Clips
31	Disposable Cartridge for Automatic Clip Applier Model No. see ATTACHMENT 31-List of
32	Product Name: Disposable Endoscopic Surgical Scissor Trade Name: Disposable Endoscopic Surgic Instrument Model No: 0208-DS01XX,0208-DS02XX,0208-DS03XX
33	Product Name: Disposable Endoscopic Surgical Dissector Trade Name: Disposable Endoscopic Surgi Instrument Model No: 0208-DD01XX,0208-DD01RX see ATTACHMENT32-List of Active Medica
34	Product Name: Disposable Endoscopic Surgical Grasper Trade Name: Disposable Endoscopic Surg Instrument Model No: 0208-DG01RX,0208-DG02RX,0208-DG03RX,0208-DG04RX,0208-DG05RX,02 DG02RXB,0208-DG04RXB,0208-DG05RX
35	Product Name: Reusable Endoscopic Surg Scissor Trade Name: Reusable limited use endoscopic surgical instrument Model No: 0207-LS01XF,0207-LS02XF,0207-LS03XF,0207-LS01XFB



36	Product Name: Reusable Endoscopic Surgica Dissector Trade Name: Reusable limited use endoscopic surgical instrument Model No.: 0207-LD01XF,0207- LD01RF,0207- LD01RFB
37	Product Name: Reusable Endoscopic Surgica Grasper Trade Name: Reusable limited use endoscopic surgical instrument Model No.: 0207-LG01RF,0207- LG02RF,0207- LG03RF,0207-LG04RF,0207-LG05RF,0207- LG04RFB,0207-LG05RFB
38	Product Name: Reusable Electrosurgery Instrument Kits-Handle Trade Name: Reusable detachable endoscopic surgical instrument Model No.: 0207-HR,0207-HX see ATTACHMENT32-List of Active Medical
39	Product Name: Reusable Electrosurgery Instrument Kits-Shaft Trade Name: Reusable detachable endoscopic surgical instrument Model No.: 0207-S05UN see ATTACHMENT32-List of Active Medical
40	Product Name: Reusable Electrosurgery Instrument Kits- Scissor Jaw (Insert) Trade Name: Reusable detachable endoscopic surgical instrument Model No.:0207-IS01,0207-IS02,0207-IS03 see ATTACHMENT32-List of Active Medical
41	Product Name: Reusable Electrosurgery Instrument Kits- Dissector Jaw (Insert) Trade Name: Reusable detachable endoscopic surgical instrument Model No.: 0207-ID01 see ATTACHMENT32-List of Active Medical



42	Product Name: Reusable Electrosurgery Instrument Kits-Grasper Jaw (Insert) Trade Name: Reusable detachable endoscopic surgical instrument Model No.:0207-IG01,0207-IG02,0207-IG03,0207-IG04,0207-IG05 see ATTACHMENT32-List of Active Medical

Please add or delete lines as required!

Product List and Application MDR QM part	TÜVRheinland®

Qingdao	2023/4/19	
Location	Date	Legally binding signature

The Notified Body TÜV Rheinland LGA Products GmbH confirms that the information provided on the Product List and Application is covered by the EU conformity assessment procedure as certified by MDR (EU) certificate No: _____

Date	Signature (certifier of the Notified Body)