EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60147743 0001

Report No.: 15045630 014

Manufacturer:
Huaian Tianda Medical
Instruments Co., Ltd.
No.106, East Songjiang Road,
Huaiyin Economic & Technological
Development Zone
223002 Huaian City, Jiangsu
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60113937 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-10-08

Date: 2020-10-08

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Digitally signed by Potînga Stela
Date: 2026.05.06 15:10:59 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60147743 0001
Report No.: 15045630 014

Manufacturer:
Huaian Tianda Medical Instruments Co., Ltd.
No.106, East Songjiang Road,
Huaiyin Economic & Technological Development Zone
223002 Huaian City, Jiangsu
P.R. China

Products:

- Disposable Surgical Blades (with and without handle)
- Sterile Blood Lancets
- Disposable Safety Lancets
- Alcohol Pads

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Umbilical Cord Clamps
- Urine Bags

Notified Body

Date: 2020-10-08

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Huaian Tianda Medical Instruments Co., Ltd.
No.106, East Songjiang Road,
Huaiyin Economic&Technological Development Zone,
Huaian City 223300, Jiangsu
P.R. China

Contact

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

Date April 19, 2024

Notified Body Confirmation Letter
Reference. : 244592151

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Huaian Tianda Medical Instruments Co., Ltd.
No.106, East Songjiang Road,
Huaiyin Economic&Technological Development Zone,
Huaian City 223300, Jiangsu
P.R. China
SRN Number: CN-MF-000031504

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

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

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Herbert Zhong
Certification body

Herbert Zhong
2024.04.19
'00'08+ 08:56:36

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Disposable Surgical Blades（9、10、10A、11、12、12B、12D、13、14、15、15A、15C、15D、16、18、19、20、21、22、22A、23、24、25、25A、26、27、34、36） **Basic UDI-DI: 69519338SBGV**	Class IIa	Disposable Surgical Blades (with and without handle) Model: 9#、10#、11#、12#、15#、17#、20#、21#、22#、23#、24#、24d#、34#）	Certificate # DD 60147743 0001; NB# 0197
Disposable Surgical Blades (with handle)（9、10、10A、11、12、12B、12D、13、14、15、15A、15C、15D、16、18、19、20、21、22、22A、23、24、25、25A、26、27、34、36） **Basic UDI-DI:**	Class IIa	Disposable Surgical Blades (with and without handle) Model: 9#、10#、11#、12#、15#、17#、20#、21#、22#、23#、24#、24d#、34#）	Certificate # DD 60147743 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
69519338DSGJ			
Sterile Blood Lancets - Twist(21G, 23G, 26G, 28G, 30G) **Basic UDI-DI: 69519338BLFW**	Class IIa	Sterile Blood Lancets Model: Twisting	Certificate # DD 60147743 0001; NB# 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NA	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-4-19	244592151	Initial issue

Product List and Application MDR

(EU) 2017/745 Annex IX and XI

Including an application according to (EU) 2023/607 -
extension of MDD certification for devices intended to be transferred to MDR

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Name of Legal Manufacturer (shall be identical as given in General Agreement with TRLP):	Huaian Tianda Medical Instruments Co., Ltd.
Additional registered trade name or registered trade mark of the manufacturer (used on the label; MDR Annex I clause 23.2.c):	(only if applicable)
Address of Legal Manufacturer:	No.106, East Songjiang Road, Huaiyin Economic&Technological Development Zone, Huaian City 223300,Jiangsu P.R. China
EUDAMED Single Registration No:	CN-MF-000031504
MDR (EU) 2017/745:	Annex IX Chapter I and II
Reason for submission:	Application according to (EU) 2023/607 (may also be an Initial application MDR)

☑ **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 list only devices for which EU 2023/607 Confirmation Letter is requested)

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.

Product List and Application MDR

(EU) 2017/745 Annex IX and XI

Including an application according to (EU) 2023/607 -
extension of MDD certification for devices intended to be transferred to MDR

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Declaration of the applicant

I hereby apply for the assessment of my quality management/assurance system and the technical documentationwith 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:

- I ensure and declare that the class IIa devices in question are manufactured in conformity with the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

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 and the technical documentation as defiend in Annex II and III;
- 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 inform TÜV Rheinland LGA Products GmbH about any planned substantial change to the approved devices (i.e. those which may affect conformity with the general safety and performance requirements), to the approved design of the device, to the intended use of or claims made for the device, with the conditions prescribed for use of the product or to any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures in accordance with referred to in Sections 5 and 6 of Annex IX, applicable only for the devices covered by certificate to MDR 2017/745 Annex IX, Chapter II

- 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

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

(EU) 2017/745 Annex IX and XI

Including an application according to (EU) 2023/607 -
extension of MDD certification for devices intended to be transferred to MDR

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FACILITIES:

Code of facility	Scope of facility	Legal entity name of facility	Address of facility	EUDAMED Single Registration No
EAR(1)	European authorised Representative	RIOMAVIX SOCIEDAD LIMITADA	Calle de Almansa 55, 1D, Madrid 28039 Spain	ES-AR-000001202
IMF(1)	Internal Manufacturing Facility	Huaian Tianda Medical Instruments Co., Ltd.	No.106, East Songjiang Road, Huaiyin Economic&Technological Development Zone, Huaian City 223300,Jiangsu P.R. China	
EMF(1)	External Manufacturing Facility			
IR&D(1)	Internal Research & Development	Huaian Tianda Medical Instruments Co., Ltd.	No.106, East Songjiang Road, Huaiyin Economic&Technological Development Zone, Huaian City 223300,Jiangsu P.R. China	
ER&D(1)	External Research & Development			
S_RAD(1)	Sterilization facility Radiation : Electron beam	Zhangjiagang Municipal CNNC Huakang Radiation Co,Ltd.	Chuangye Road, Fenghuang Town, 215614 Zhangjiagang, PEOPLE'S REPUBLIC OF CHINA	
S_GAS(1)	Sterilization facility Gas - Please select method			
S_HEAT(1)	Sterilization facility Heat - Please select method			
S_OTH(1)	Sterilization 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),...

Product List and Application MDR

(EU) 2017/745 Annex IX and XI

Including an application according to (EU) 2023/607 -
extension of MDD certification for devices intended to be transferred to MDR

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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)	Type of device using terminology of Basic-UDI-DI, EMDN or GMDN	Basic UDI-DI code	Medical Device Category (for all medical devices)	European Medical Device Nomenclature (EMDN) *Please use EMDN code 4th level (EMDN code on level 4, Letter + 5 digits, if no level 4 exists, use next upper level)*	Classification of product and classification rule resulting in highest risk class		Summary list of related facilities *(use facility codes from Facilities table, i.e. IMF(1), IR&D(1))*	Code of EU-REP *(use facility No. from Facilities table)*	Technical Documentation identifier *(if the TD is ready for submission)* **or** declared date of submission of the technical documentation **[YYYY-MM]** *(if the TD is not ready yet for submission)*	Regulation (EU) 2023/607	
						Device Class	Classification Rule including subclause according to Annex VIII				If the MDR device is intended to substitute legacy device, identification of the corresponding MDD/AIMDD device *Please list the devices covered by the current MDD certificate which are intended to be discontinued but to be substituted by the device as specified in columns B.*	MDD/AIMD Certificate(s) reference of the devices under MDR application and the notified body Identification *Please refer to the MDD/AIMD certificate(s) covering devices listed in columns B and/or E*
1	Disposable Surgical Blades（9、10、10A、11、12、12B、12D、13、14、15、15A、15C、15D、16、18、19、20、21、22、22A、23、24、25、25A、26、27、34、36）	SCALPELS WITHOUT SAFETY SYSTEMS, SINGLE-USE	69519338SBGV	MDN 1208 Non-active non-implantable instruments	V010102	IIa	Rule 6 No indent	IMF(1),IR&D(1),S_RAD(1)	EAR(1)	TD-CE/001	Disposable Surgical Blades (with and without handle) Model: 9#、10#、11#、12#、15#、17#、20#、21#、22#、23#、24#、24d#、34#)	DD 60147743 0001 #0197
2	Disposable Surgical Blades (with handle)（9、10、10A、11、12、12B、12D、13、14、15、15A、15C、15D、16、18、19、20、21、22、22A、23、24、25、25A、26、27、34、36）	SCALPELS WITH SAFETY SYSTEMS, SINGLE-USE	69519338DSGJ	MDN 1208 Non-active non-implantable instruments	V010101	IIa	Rule 6 No indent	IMF(1),IR&D(1),S_RAD(1)	EAR(1)	TD-CE/001	Disposable Surgical Blades (with and without handle) Model: 9#、10#、11#、12#、15#、17#、20#、21#、22#、23#、24#、24d#、34#)	DD 60147743 0001 #0197
3	Sterile Blood Lancets - Twist(21G, 23G, 26G, 28G, 30G)	LANCETS WITHOUT SAFETY SYSTEMS, SINGLE-USE	69519338BLFW	MDN 1208 Non-active non-implantable instruments	V010402	IIa	Rule 6 No indent	IMF(1),IR&D(1),S_RAD(1)	EAR(1)	TD-CE/002	Sterile Blood Lancets Model: Twisting	DD 60147743 0001 #0197
4	Sterile Blood Lancets - Safety(18G ,21G, 23G, 26G, 28G, 30G,)	LANCETS WITH SAFETY SYSTEMS, SINGLE-USE	69519338HSS2XT	MDA 0318 Other active non-implantable devices	V010401	IIa	Rule 6 No indent	IMF(1),IR&D(1),S_RAD(1)	EAR(1)	TD-CE/002	N/A	first application, no MDD cert.
5	Umbilical Cord Clamps（50mm,55mm）	UMBILICAL CLAMPS AND CLIPPERS, SINGLE-USE	69519338UCC6P	MDN 1208 Non-active non-implantable instruments	V0202	Is	Rule 1 No indent	IMF(1),IR&D(1),S_RAD(1)	EAR(1)	2025.04	N/A	first application, no MDD cert.
6	Urine Bags（Push-pull,T-value）	URINE COLLECTION SYSTEMS AND BAGS, SINGLE-USE	69519338UBH3	MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	A060303	Is	Rule 1 No indent	IMF(1),IR&D(1),S_RAD(1)	EAR(1)	2025.04	N/A	first application, no MDD cert.

Please add or delete lines as required!

Product List and Application MDR

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extension of MDD certification for devices intended to be transferred to MDR

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For the devices of class Ir, Im, Is, IIa, IIb and III custom-made implantable, the application is limited to MDR 2017/745 Annex IX, Chapter I.

Huai'An	4/15/2024	
Location	Date	Legally binding signature

With signature of this application, the applicant confirms the validity and the accuracy of the data entered into the form sheet as basis for the extension of the MDD certification covering the listed articles within the requirements and the intent of regulation (EU) 2023/607.
The applicant also acknowledges that the general agreement executed between the manufacturer and TÜV Rheinland LGA Products GmbH (TRLP) on certification services including the signed PZO applies also to all activities undertaken in execution of regulation (EU) 2023/607 resulting from this application, thus confirming that this application also fulfills the requirement defined in (EU) 2023/607 that there be a written agreement in place between legal manufacturer and Notified Body latest by September 26, 2024.

The Notified Body TÜV Rheinland LGA Products GmbH confirms receipt of the application for conformity assessment procedure.

Herbert Zhong '00'08+ 08:55:24 2024.04.19	
Date	Signature (certifier of the Notified Body)

The Notified Body TÜV Rheinland LGA Products GmbH confirms that the infomation 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)

Hardcopy Original
TUVR Shanghai
RJ 2024-06-17