EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.:	HD 2184123-1
Manufacturer:	Shenzhen Lanmage Medical Technology Co., Ltd. No.103, Baguang Service Center, No.2 Baisha Bay Road, Baguang Community, Kuichong Subdistrict, Dapeng New District Shenzhen 518119 Guangdong P.R. China
Products:	Ultrasound Diagnostic Scanners, X-ray Radiography Systems, Digital Flat Panel Detectors

Digitally signed by Antonova Anna
Date: 2026.04.23 15:35:08 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.:	10918612-100
Effective date:	2021-04-22
Expiry date:	2024-05-26
Issue date:	2021-04-22

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2184123-1

Manufacturer:
Shenzhen Lanmage Medical
Technology Co., Ltd.
No.103, Baguang Service Center,
No.2 Baisha Bay Road,
Baguang Community, Kuichong Subdistrict,
Dapeng New District
Shenzhen
518119 Guangdong
P.R. China

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	Shenzhen Lanmage Medical Technology Co., Ltd. 1st Floor, Building B, Jingchengda Industrial Park, No. 4 keji road, Langxin Community, Shiyan Street, Bao'an District, Shenzhen, 518000 Guangdong P.R. China	Ultrasound Diagnostic Scanners, X-ray Radiography Systems, Digital Flat Panel Detectors

Report No.: 10918612-100

Effective date: 2021-04-22

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

EC Declaration of Conformity

Manufacturer:

Shenzhen Lanmage Medical Technology Co., Ltd.

No.103, Baguang Service Center, No.2 Baisha Bay Road, Baguang Community, Kuichong Subdistrict, Dapeng New District, Shenzhen, 518119 Guangdong, P.R. China

whose single Authorized Representative:

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

We, the manufacturer, herewith declare that

the medical device:

Digital Color Doppler Diagnostic Scanner
Model:EX20/EX20e/EX20i/EX20c/CK 35/CK 35S/CK 35T/TP 55/TP 55S/ TP 55E/CV 65/CV 65S/CV 65P/CV85/CV80/CV75/CV70/CV55/CV50/CV45/CV40/CV35/CV30
Class: IIa
Ultrasound Color Doppler Diagnostic Scanner
Model:Mirror2 Touch/Mirror5 Touch/Mirror8 Touch
Class: IIa
Digital Color Doppler Diagnostic System
Model:C6/C6 Pro/C6 exp/C5/C5 Pro/C5 exp/C6 B/W
Class: IIa
Digital Flat panel Detector
Model:LWTC-F1M/Wiser-01/Wiser-12/Wiser-13/Wiser-14
Class: IIa
Ultrasound Diagnostic Scanner
Model:F40/F50/F60/C20/C25/C30/C40/P09/P09 Exp/P09 Pro/CU30/CU40/ CU50/CU60/Mirror2/Mirror2 HD/Mirror2 Plus/Mirror2 Pro/Mirror5/ Mirror5Exp/Mirror5 Pro
Class: IIa
Digital X-ray Radiography System
Model:6600/6600A/6600B/6600C/6600D/6600E/Keen Ray DR2800F/6100B/9100K/9100K3/9100L2
Class: IIb,GMDN code:37645
Mobile Digital X-ray Radiography System
Model:Keen Ray DR50M/Keen Ray DR200Mate/7200A/7200B/ Keen RayDR200Mate e/Keen Ray DR200Mate Plus
Class: IIb, GMDN code:37647
Digital Multifunction X-ray Fluorography System
Model:7500,7600,7700
Class: IIb
Digital Mammography System
Model:8100A,8100B

Class: IIb

Meets the provisions of Directive 93/42/EEC and its transpositions in national laws which apply to it.The declaration is valid connection with the "final inspection report"of the device.

The medical device has been assigned to Class: IIa/ Class IIb according to rule 10 and rule 16 Annex IX of Directive 93/42/EEC.

It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TUV Rheinland LGA Products GmbH,
Tillystra β e 2 • 90431 Nürnberg • Germany
Certificate No.:HD 2184123-1
Notified Body Confirmation Letter Reference.:10924187
Issue date: 13.03.2024
Expiry date: 30.12.2028

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of

Shenzhen Lanmage Medical Technology Co., Ltd.

Shenzhen, China July 2, 2024

Place , date

Jie Zheng, Deputy general manager
Name and function

APPENDIX: List of product standards

Item	Scope	Number of standard	Name of standard
1	General, Safety	IEC60601-1:2005+A1:2012+A2:2020 EN60601-1:2006+A1:2013+A12:2014 +A2:2021	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
2	General, EMC	IEC60601-1-2:2014+A1:2020 EN 60601-1-2:2015+A1:2021	Medical electrical equipment --Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic disturbances - Requirements and tests

3	General, Usability	EN 60601-1-6:2010/A2:2021	Medical electrical equipment –Part 1-6: General requirements for basic safety and essential performance –Collateral standard: Usability.
4	General, Usability	EN 62366-1:2015/A1:2020	Medical device –Part 1: Application of usability engineering to medical devices
5	Safety	IEC60601-2-37:2007+A1:2015 EN 60601-2-37:2008+A1:2015	Medical Electrical Equipment Part 2-37: Particular Requirements for the basic safety and essential performance of Ultrasonic Medical Diagnostic and Monitoring Equipment
6	Safety	IEC60601-1-3:2008+A1:2013+A2:2021	Medical electrical equipment - Part 1-3: General requirements for safety - collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
7	Safety	EN 60601-2-54:2009+ A1:2015+A2:2019	Medical electrical equipment -- Part 2-54: Particular requirements for the basic safety and essential performance of Xray equipment for radiography and radioscopy
8	General, Software	EN 62304:2006+A1:2015	Medical device software – Software life-cycle processes.
9	Acoustic output	EN 61157: 2007+A1:2013	Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment
10	Risk management	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
11	Labeling	EN ISO 15223-1:2021	Medical devices - symbols to be used with medical device labels, labeling and information to be supplied.
12	Information	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
13	Biological evaluation	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
14	Biological evaluation	EN ISO 10993-5:2009	Biological evaluation of medical devices-- Part 5:Tests for in vitro cytotoxicity
15	Biological evaluation	EN ISO 10993-10:2023	Biological evaluation of medical devices-- Part 10:Tests for irritation and skin sensitization

Note : EN 60601-2-37:2008 +A1:2015 is applicable for Ultrasound Diagnostic Scanners , and EN

60601-1-3:2008+ A1:2013 and EN 60601-2-54:2009+ A1:2015+A2:2019 are applicable for X-ray Radiography Systems and Digital Flat panel Detectors.

Business Stream Products
Certification Department

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LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Shenzhen Lanmage Medical Technology Co., Ltd.
No.103, Baguang Service Center, No.2 Baisha
Bay Road, Baguang Community, Kuichong
Subdistrict, Dapeng New District,
Shenzhen, 518119, Guangdong,
P.R. China

Contact

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

Date March 13, 2024

Notified Body Confirmation Letter
Reference. : 10924187

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:

Shenzhen Lanmage Medical Technology Co., Ltd.
No.103, Baguang Service Center, No.2 Baisha
Bay Road, Baguang Community, Kuichong
Subdistrict, Dapeng New District,
Shenzhen, 518119, Guangdong,
P.R. China
SRN Number (if available): CN-MF-000001122

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

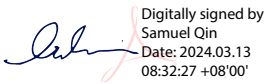
Tillystraße 2
90431 Nuremberg

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



Samuel Qin

Certification body

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**
Digital X-ray Radiography System Model: 6600B, 6100B,9100K, 9100K3, 9100L2 **Basic UDI-DI:** 697129745001LE	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2184123-1 NB#0197 Note: Models 9100K, 9100K3, 9100L2 are not covered by MDD certificate.
Mobile Digital X-ray Radiography System/ c-arm Model: 7200A,7200A2 **Basic UDI-DI:** 697129745002LG	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2184123-1 NB#0197 Note: Models 7200A2 is not covered by MDD certificate.
Digital X-ray Radiography System Model:	Class IIb excluding Class IIb	N/A	Certificate # HD 2184123-1

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**
6600, 6600A, 6600C, 6600D, 6600E, Keen Ray DR2800F, 7500, 8100A, 8100B **Basic UDI-DI:** 697129745003LJ	implantable non-WET		NB#0197
Mobile Digital X-ray Radiography System Model: Keen Ray DR50M, 7200B, Keen Ray DR200Mate, Keen Ray DR200Mate e, Keen Ray DR200Mate Plus **Basic UDI-DI:** 697129745004LL	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2184123-1 NB#0197
Digital Flat Panel Detector Model: LWTC-F1M, Wiser-01, Wiser-12 **Basic UDI-DI:** 697129745005LN	Class IIa	Flat Panel Detector Model: Wiser-01 Dynamic Flat Panel Detector Model: Wiser-12	Certificate # HD 2184123-1 NB#0197
Wireless Digital Flat Panel Detector Model: Wiser-13, Wiser-14 **Basic UDI-DI:** 697129745006LQ	Class IIa	N/A	Certificate # HD 2184123-1 NB#0197
Ultrasound Diagnostic Scanner Model: Mirror2, Mirror2 Plus, Mirror2 Pro, Mirror2 HD, Mirror5, Mirror5 Pro, Mirror5 Exp, Mirror2 Touch, Mirror5 Touch, Mirror8 Touch **Basic UDI-DI:** 697129745007LS	Class IIa	Ultrasound Color Doppler Diagnostic Scanner Model: Mirror2 Touch, Mirror5 Touch, Mirror8 Touch	Certificate # HD 2184123-1 NB#0197
Digital Color Doppler Diagnostic Scanner Model: EX20, EX20e, EX20i, EX20c, CV 65, CV	Class IIa	N/A	Certificate # HD 2184123-1 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
65S, CV 65P, CV85, CV80, CV75, CV70, CV55, CV50, CV45, CV40, CV35, CV30 **Basic UDI-DI:** 697129745008LU			
Digital Color Doppler Diagnostic System Model: C6 Pro, C6 exp, C6, C5 Pro, C5 exp, C5, C6 B/W **Basic UDI-DI:** 697129745009LW	Class IIa	N/A	Certificate # HD 2184123-1 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
N/A	**N/A**	**N/A**	**N/A**

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-03-13	10924187	Initial issue