EC Certificate

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TÜVRheinland®

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

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
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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 Certificate

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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

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