EC Certificate

TÜVRheinland®

Full Quality Assurance System
MDD Annex II excl. 4

Registration No.:	HD 2183426-1
Manufacturer:	MinFound Medical Systems Co., Ltd. Floor 1-2, Building 5, No.129 Yifeng Road, Hangzhou Economic and Technological Development Zone, Hangzhou City, 310018 Zhejiang P.R. China
Products:	Computed Tomography (CT) Scanner Systems

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.:	15096101 013
Effective date:	2020-12-23
Expiry date:	2024-05-26
Issue date:	2020-12-23

TÜV Rheinland LGA Products GmbH
TUVRheinland®
Zertifizierungsstelle

Jason Pan
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

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Registration No.: HD 2183426-1

Manufacturer: MinFound Medical Systems Co., Ltd.
Floor 1-2, Building 5,
No.129 Yifeng Road, Hangzhou Economic and Technological Development Zone, Hangzhou City,
310018 Zhejiang
P.R. China

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	MinFound Medical Systems Co., Ltd. No.6 Dongshan Road, Jishan Street, Yuecheng District, Shaoxing City, 312099 Zhejiang P.R. China	Computed Tomography (CT) Scanner Systems

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Product List und Application MDD, AIMDD

TÜVRheinland®

Name Legal Manufacturer	MinFound Medical Systems Co., Ltd.
Address Legal Manufacturer	Floor 1-2, Building 5, No.129 Yifeng Road, Hangzhou Economic and Technological Development Zone, Hangzhou City, 310018 Zhejiang, P.R. China
MDD 93/42/EEC	Annex II excluding Section 4
Reason for submission of product list	Other changes in existing product list

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".

Product List und Application
MDD, AIMDD

TÜVRheinland®

Code of facilities	Scope of facilities	Name of facility	Address of facility	
EAR(1)	European Authorized Representative	MedNet EC-REP GmbH	Borkstrasse 10, 48163 Münster, Germany Phone: +49 251 322 66-61 Fax: +49 251 32266-22 DIMDI Code: DE/0000048589 Email: ecrep@medneteurope.com website: www.mednet-eurep.com	
IMF(1)	Internal Manufacturing Facility	MinFound Medical Systems Co., Ltd.	Floor 1-2, Building 5, No.129 Yifeng Road, Hangzhou Economic and Technological Development Zone, Hangzhou City, 310018 Zhejiang, P.R. China	
IMF(2)	Internal Manufacturing Facility	MinFound Medical Systems Co., Ltd.	No.6 Dongshan Road, Jishan Street, Yuecheng District, Shaoxing City, Zhejiang 312099, P.R. China	
EMF(1)	External Manufacturing Facility			
R&D(1)	Research & Development	MinFound Medical Systems Co., Ltd.	Floor 1-2, Building 5, No.129 Yifeng Road, Hangzhou Economic and Technological Development Zone, Hangzhou City, 310018 Zhejiang, P.R. China	
R&D(2)	Research & Development	MinFound Medical Systems Co., Ltd.	No.6 Dongshan Road, Jishan Street, Yuecheng District, Shaoxing City, Zhejiang 312099, P.R. China	

Reference **MinFound Medical Systems Co., Ltd. / 2021-01-28**

OEM(1)	Original Equipment Manufacturer		
Sterilization facility Radiation (1)			
Sterilization facility Gas(1)			
Sterilization facility Heat(1)			
Sterilization facility: Other sterilization methods(1)			

Product List und Application
MDD, AIMDD

TÜVRheinland®

Please enter product details below or use a separate controlled list which makes reference to this application (e.g. by refering to the application date)

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]
X-ray Computed Tomography System ScintCare CT16 (16 and 32 slice configuration)	Computed Tomography (CT) Scanner Systems	Rule 10, 3.2.4	IIb	MD 1201 Imag	Full body CT system	37618	MF/CE01		IMF(1);IMF(2);R&D(1);R&D(2);	EAR(1)
X-ray Computed Tomography System ScintCare CT 128 (64 and 128 slice configuration)	Computed Tomography (CT) Scanner Systems	Rule 10, 3.2.4	IIb	MD 1201 Imag	Full body CT system	37618	MF/CE02		IMF(1);IMF(2);R&D(1);R&D(2);	EAR(1)
X-ray Computed Tomography System ScintCare Blue 755 (16 and 32 slice configuration)	Computed Tomography (CT) Scanner Systems	Rule 10, 3.2.4	IIb	MD 1201 Imag	Full body CT system	37618	MF/CE03		IMF(1);IMF(2);R&D(1);R&D(2);	EAR(1)
X-ray Computed Tomography System ScintCare CT 16E(16 and 32 slice configuration)	Computed Tomography (CT) Scanner Systems	Rule 10, 3.2.4	IIb	MD 1201 Imag	Full body CT system	37618	MF/CE04		IMF(1);IMF(2);R&D(1);R&D(2);	EAR(1)

Reference **MinFound Medical Systems Co., Ltd. / 2021-01-28**

Product List und Application
MDD, AIMDD

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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]
X-ray Computed Tomography System QuantumEye 789 (configuration 1:256 slice (128-row) configuration 2: 256 slice (256-row) configuration 3: 512 slice (256- row))	Computed Tomography (CT) Scanner Systems	Rule 10, 3.2.4	IIb	MD 1201 Imag	Full body CT system	37618	MF/CE05		IMF(1);IMF(2);R&D (1);R&D(2);	EAR(1)

Date 28.01.2021

Location Hangzhou

Legally binding signature

Gesehen/Reviewed
Shanghai. 2021-01-29 Katrina
TÜV Rheinland LGA Products GmbH

Reference **MinFound Medical Systems Co., Ltd. / 2021-01-28**