

Certificate

Quality Management System EN ISO 13485:2016

Registration No.:

SX 2183426-1

Organization:

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 also covers the following:

No.	Facility	Scope
/01	MinFound Medical Systems Co., Ltd. No.6 Dongshan Road, Jishan Street, Yuecheng District, Shaoxing City, 312099 Zhejiang P.R. China	Design and Development, Manufacture and Distribution of Computed Tomography (CT) Scanner Systems, Positron Emission Tomography/Computed Tomography (PET/CT) Systems, Magnetic Resonance Imaging (MRI) Systems

Report No.: 15096101 012

Effective date: 2020-11-11

Expiry date: 2022-03-27

Issue date: 2020-11-11





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



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Organization: MinFound Medical Systems Co., Ltd.

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Scope: Design and Development, Manufacture and Distribution of Computed

Tomography (CT) Scanner Systems, Positron Emission

Tomography/Computed Tomography (PET/CT) Systems, Magnetic

Resonance Imaging (MRI) Systems

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

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DAKKS

Deutsche
Akkreditierungsstelle
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