

EC Certificate



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

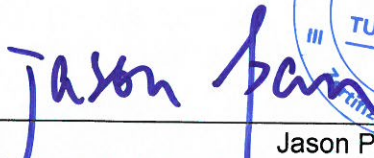
The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, 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


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.

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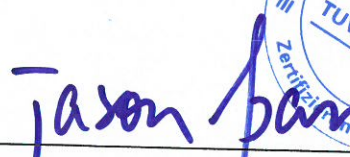
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310018 Zhejiang
P.R. China

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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A circular seal of TÜV Rheinland LGA Products GmbH. It features the company logo in the center, surrounded by the text "TÜV Rheinland LGA Products GmbH" and "Zertifizierungsstelle".

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