



Declaration of Conformity

Manufacturer: MinFound Medical Systems Co., Ltd
Site1(holder): Floor 1-2, Building 5, No.129 Yifeng Road, Hangzhou Economic and Technological Development Zone, Hangzhou City, 310018 Zhejiang, P.R. China
Manufacturing Sites: Site 2: No. 6 Dongshan Road, Jishan Street, Yuecheng District, Shaoxing City, 312099 Zhejiang, P.R. China

European Representative: MedNet EC-REP GmbH
Borkstrasse 10• 48163 Muenster• Germany

Product Name: X-ray Computed Tomography System
Specification: ScintCare Blue 755 ; ScintCare CT 128; ScintCare CT 16;
ScintCare CT 16E ; QuantumEye 789
GMDN Code: 37618

Classification (MDD, Annex IX): Class IIb, Rule 10
Conformity Assessment Route: Annex II without (4)

We, the manufacturer herewith declare on our own responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
NB Identification number: 0197
(EC) Certificate(s): HD 2183426-1
Expire date of the Certificate: 2024-05-26

This Declaration of Conformity is valid in connection with the release document for the respective batch of produced devices.

Harry Jiang , CEO

(name and signature or equivalent
marking of authorized person)

Shaoxing, 2021-05-08

(place and date of issue)