Declaration of Conformity

Manufacturer:

MinFound Medical Systems Co., Ltd

Manufacturing

Sites:

Site1(holder): Floor 1-2, Building 5, No.129 Yifeng Road, Hangzhou Economic and Technological Development Zone,

Hangzhou City, Zhejiang Province, China

Site 2: No.6 Dongshan Road, Jishan Street, Yuecheng District, Shaoxing City, Zhejiang Province, China

European

Representative

MedNet EC-REP GmbH

Borkstrasse 10 · 48163 Muenster · Germany

Product Name: Specification:

X-ray Computed Tomography System

ScintCare Blue 755; ScintCare CT 128; ScintCare CT 16

GMDN Code:

37618

Classification (MDD, Annex IX): 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

Place, Date of Issue:

Shaoxing, 2021-01-05

Signature:

Name:

Harry Jiang

Position:

CEO