EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60113201 0001

Report No.: 15094128 001

Manufacturer:
Nanjing Perlove Medical
Equipment Co., Ltd.
No.168, Kaiyuan Road
Jiangning District
211100 Nanjing
China

Products:
Diagnostic X-ray System, X-ray Tube Assembly

Replaces Approval, Registration No.: HD 60112353 0001

Expiry Date: 2021-08-21

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.

Effective Date: 2016-08-29

Date: 2016-08-29

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle Notified Body

C. Liu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.