

EC Certificate

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

Registration No.:

HD 2027461-1

Manufacturer:

Nanjing Perlove Medical Equipment

Co., Ltd.

No. 97 and No. 99 Wangxi Road,

Jiangning District, Nanjing,

211100 Jiangsu P.R. China

Products:

Diagnostic X-ray System

Replaces Approval, Registration No.: HD 60130054 0001

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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.:

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TÜVRheinland III

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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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