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TÜVRheinland®

EC Certificate

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

Registration No.: HD 60145360 0001

Report No.: 12031241 013

Manufacturer:
Canon Electron Tubes &
Devices Co., Ltd.
1385, Shimoishigami, Otawara-shi
Tochigi
324-8550 Japan

Products:
X-ray Tubes, X-ray Tube Assemblies, X-ray Image Intensifiers and X-ray Flat Panel Detectors

Replaces Approval, Registration No.: HD 60133586 0001

Expiry Date: 2024-05-26

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: 2019-12-20

Date: 2019-12-20

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Notified Body

T. Matsuda
Takashi Matsuda

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.