EC Certificate

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

Registration No.: HD 60143874 0001

Report No.: 12031293 014

Manufacturer:
Canon Medical Systems Corporation
1385, Shimoishigami
Otawara-shi, Tochigi
324-8550 Japan

Products:
see attachment for products included

Replaces Approval, Registration No.: HD 60125549 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: 2019-11-07

Date: 2019-11-07

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

M. Aihara

M.Sc. M. Aihara

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.

Digitally signed by Matei Vasile
Date: 2023.07.24 10:34:25 EEST
Reason: MoldSign Signature
Location: Moldova

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60143874 0001
Report No.: 12031293 014

Manufacturer: Canon Medical Systems Corporation
1385, Shimoishigami
Otawara-shi, Tochigi
324-8550 Japan

Products included:

- Mobile and Stationary Diagnostic X-Ray Systems
- Mobile and Stationary Fluoroscopic X-Ray Systems
- X-Ray Computed Tomography Systems
- Diagnostic Ultrasound Systems
- Magnetic Resonance Imaging Systems
- Positron CT System combined with X-ray CT Scanner
- Workstation Software for Diagnostic X-Ray Systems
- Workstation Software for Diagnostic X-Ray Computed Tomography Systems
- Workstation Software for Diagnostic Ultrasound Systems
- Workstation Software for Diagnostic Magnetic Resonance Imaging Systems

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Notified Body

Date: 2019-11-07

M.Sc. M. Aihara

Certificate

The SQS herewith attests that the organisation named below has a management system that meets the requirements of the normative basis mentioned.

Pearl Technology AG
Wiesenstrasse 33
8952 Schlieren
Switzerland

Scope

Development, manufacturing and distribution of patient positioning systems

Normative basis

EN ISO 13485:2016 Medical devices – Quality Management System

Reg. no. 43529
Page 1 of 1

Validity 01.02.2023 – 31.01.2026
Issue 01.02.2023

A. Grisard, President SQS

F. Müller, CEO SQS

sqs.ch

Swiss Association for Quality and Management Systems (SQS)
Bernstrasse 103, 3052 Zollikofen, Switzerland

Swiss Made

Member of IQNET

4170_2/Januar2022_Version 3.0