EC Certificate Full Quality Assurance System: Certificate JP19/040492

The management system of

Anzai Medical Co., Ltd.

Technical Dept. of Head Office

3-9-15, Nishi-Shinagawa, Shinagawa-ku,
Tokyo 141-0033 Japan

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

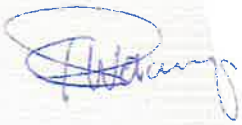
The scope of registration appears on page 2 of this certificate.

This certificate is valid from 28 August 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 23 January 2003
and first certificates by SGS Belgium on 28 August 2019
Re certification audit due before 27 March 2022

Certification is based on reports numbered JP/YOK 1760

This is a multi-site certification.
Additional site details are listed on subsequent pages

Authorised by



Pieter Weterings
Certification Manager

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Anzai Medical Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 1

Detailed scope

Respiratory Gating System (AZ-733VI) for imaging diagnosis and radiation therapy

Additional facilities

Head Office	**3-6-25, Nishi-Shinagawa, Shinagawa-ku, Tokyo, 141-0033 Japan**
Second Technical Dept.	**2-6-9, Osaki, Shinagawa-ku, Tokyo, 141-0032 Japan**