Medical Device Full Quality Assurance System Certificate JP23/00000218

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

Part II of The Medical Device Regulations 2002 Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Device Regulations 2002]

For the following products
Respiratory Gating System for imaging diagnosis and radiation therapy (AZ-733VI)

Where the above scope includes class III medical device(s), a valid Design Examination Certificate according to Annex II (Section 4) [as modified by Part 2 of Schedule 2A of The MDR 2002] is a mandatory requirement for each device in addition to this certificate to place that device on the market
Certification is based on reports numbered JP/YOK/1760
Previous certificate number: N/A
Change in between this certificate and previous one: N/A

This certificate is valid from 26 June 2023 until 26 June 2028 and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 26 June 2023
Certified activities performed by additional sites are listed on subsequent pages.

L Henderson

Authorised by
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Anzai Medical Co., Ltd.

Part II of The Medical Device Regulations 2002 Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Device Regulations 2002]

Issue 1
Sites
Anzai Medical Co., Ltd. Technical Dept. of Head Office: 3-9-15 Nishi-Shinagawa, Shinagawa-ku, Tokyo, 141-0033 Japan
Anzai Medical Co., Ltd. Head Office: 3-6-25 Nishi-Shinagawa, Shinagawa-ku, Tokyo, 141-0033 Japan
Anzai Medical Co., Ltd. Second Technical Dept.: 2-6-9 Osaki, Shinagawa-ku, Tokyo, 141-0032 Japan