CANON ELECTRON TUBES
& DEVICES CO., LTD.

CE

Instructions For Use
X-ray Image Intensifier

No. EEN-IFU019-01_Rev.1

0.Scope

This document is provided to meet the requirements in Section 23.4 of Annex I and the related sections of

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices,
amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

and its subsequent amendments.

Objective areas and countries of this document are EEA, Switzerland and Turkey.

1. CETD Device Category

X-ray Image Intensifier

2. Manufacturer name

Canon Electron Tubes & Devices Co., Ltd.

3. Name:

X-ray Image Intensifier E5759HD-P1
X-ray Image Intensifier E5764HD-P3
X-ray Image Intensifier E5764SD-P1A
X-ray Image Intensifier E5764SD-P3
X-ray Image Intensifier E5764SD-P3A
X-ray Image Intensifier E5764SD-P4A
X-ray Image Intensifier E5764SD-P6A
X-ray Image Intensifier E5796SD-H1
X-ray Image Intensifier E5796SD-P10A
X-ray Image Intensifier E5796SD-P11A
X-ray Image Intensifier E5796SD-P1A
X-ray Image Intensifier E5796SD-P2A
X-ray Image Intensifier E5796SD-P7A
X-ray Image Intensifier E5804SD-P3
X-ray Image Intensifier E5830SD-P4
X-ray Image Intensifier E5830SD-H5
X-ray Image Intensifier E5830SD-H6
X-ray Image Intensifier E5830SD-H7
X-ray Image Intensifier E5830SD-P10A

X-ray Image Intensifier E5830SD-P11A
X-ray Image Intensifier E5830SD-P1A
X-ray Image Intensifier E5830SD-P3A
X-ray Image Intensifier E5830SD-P4A
X-ray Image Intensifier E5830SD-P6A
X-ray Image Intensifier E5830SD-P7
X-ray Image Intensifier E5830SD-P7A
X-ray Image Intensifier E5870SD-P1
X-ray Image Intensifier E5876SD-P1A
X-ray Image Intensifier E5876SD-P2A
X-ray Image Intensifier LIF-09
X-ray Image Intensifier RTP12302J-G10
X-ray Image Intensifier RTP12302J-G9
X-ray Image Intensifier RTP14301J-G1E
X-ray Image Intensifier RTP16301J-G1E
X-ray Image Intensifier RTP9206J-P9

4. Registered place of business:

1385, Shimoishigami, Otawara-shi, Tochigi 324-8550, Japan

5. About medicinal substance, including a human blood or plasma derivative, or tissues or cells of animal origin, or their derivatives:

There is neither inclusion nor combination of the substances.

6. About CMR substances and endocrine-disrupting substances:

The substance is not included in the part (contact part) that may affect the user and patient.
Also, there is neither residual risk information nor preventive measures information.

7. Storage /handling condition:

・Under Operating:

Temperature	5~40℃
Humidity	30~85%
Pressure	70~106kPa

・Under Shipping and Storage:

Temperature	-15~45℃
Humidity	10~85%
Pressure	50～106kPa

8. Sterilisation:

This device is not intended to be sterilised.

9. Single use:

This device is not intended for single use.

10. The overall qualitative composition and quantitative information:

It is not a device that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body.

11. Intended purpose:

A component, X-ray image intensifier that converts X-ray pattern which pass through a patient body that reached input surface of image intensifier into corresponding light pattern. It is intended for fluoroscopy systems but is not intended for mammography.

It is not intended for recording of diagnostic images because this device does not have recording function. It shall be installed in an X-ray system with a TV camera to visualize clinical images on a monitor.

12. Indications

This X-ray image intensifier is used for fluoroscopy of X-ray image diagnosis.

13. Contra-indications:

No contra-indications

14. The patient target group or groups:

It is impossible to identify patients using with this device because the target patient group changes with the X-ray systems in which the device is installed**.**

15.Intended users:

Physicians, Radiographers, Radiological Technologists

16. Clinical benefits:

•Noninvasively and painlessly help to diagnose disease and monitor therapy,

•Support medical and surgical treatment planning and

•Guide medical personnel as they insert catheters, stents, or other devices inside the body, treat tumours, or remove blood clots or other blockages.

17. Links to EUDAMED

Not applicable since this device is not an implantable device or a class III device.

18. Performance characteristics:

Central Resolution [Lp/cm]

Model	N Mode	M1 Mode	M2 Mode	M3 Mode
E5759HD-P1	48			
E5764HD-P3	48	56	66	
E5764SD-P1A	48	56	66	
E5764SD-P3	48	56	66	
E5764SD-P3A	48	56	66	
E5764SD-P4A	48	56	66	
E5764SD-P6A	48	56	66	
E5796SD-H1	46	50	56	
E5796SD-P10A	46	50	56	
E5796SD-P11A	46	50	56	
E5796SD-P1A	46	50	56	
E5796SD-P2A	46	50	56	
E5796SD-P7A	46	50	56	
E5804SD-P3	48			
E5804SD-P4	48			
E5830SD-H5	52	58	68	
E5830SD-H6	52	58	68	
E5830SD-H7	52	58	68	
E5830SD-P10A	52	58	68	

E5830SD-P11A	52	58	68	
E5830SD-P1A	52	58	68	
E5830SD-P3A	52	58	68	
E5830SD-P4A	52	58	68	
E5830SD-P6A	52	58	68	
E5830SD-P7	52	58	68	
E5830SD-P7A	52	58	68	
E5870SD-P1	68	77		
E5876SD-P1A	46	50	56	65
E5876SD-P2A	46	50	56	65
LIF-09	48	56	66	
RTP12302J-G10	50	56	68	
RTP12302J-G9	50	56	68	
RTP14301J-G1E	42	48	56	
RTP16301J-G1E	40	46	50	60
RTP9206J-P9	48			

19. Corresponding software and accessories:

This device has no corresponding software and accessories to be selected.

20. Residual risks, contra-indications and side-effects:

It is installed into X-ray system and radiates X-rays for diagnosis.

Therefore, the side effects of exposure occur.

Residual risks

- The performance of this device gradually deteriorates with frequent use, so if any malfunction occurs, contact the X-ray manufacturer and ask the X-ray manufacturer to replace it as necessary.

21. About appropriate use of device:

This requirement is for X-ray system manufacturers.

22. Requirements for qualifications:

Physicians, Radiographers, Radiological technologists, Dentists

23. About appropriate use of device:

This requirement is for X-ray system manufacturers.

24. Reuse processes:

It is not a reusable device.

25. About reusable or not:

It is not a reusable device.

26. Combination device:

The X-ray system manufacturers or users determine the combination for other medical devices to be combined with the X-ray system.

For connection to the power supply unit, documents are provided to the X-ray system manufacturer, and for connection to the camera, mechanical and optical information is also provided.

The user is not involved in this part.

27. Radiation:

The device does not emit radiation for medical purposes.

28. Warnings, precautions, contra- indications:

28.1. Measures to be taken in the event of malfunction that may affect safety:

The X-ray image intensifier may stop operating suddenly due to its life or unexpected failure. If any defect was found in the X-ray image intensifier, stop using it immediately and according to the instructions for handling the defect and failure described in the instruction for use of the X-ray system manufacturer.

28.2. External influences:

X-ray image intensifiers may cause image distortion and resolution degradation when affected by an external magnetic field, so give consideration to reduce the effects of external magnetism (including geomagnetism).

28.3. Affecting other equipment:

Notifying the X-ray system manufacturer to evaluate electromagnetic interference.

28.4. Substance to be delivered:

It is not a device intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances.

28.5. Medicinal substance or biological material:

The medicinal substances or biological materials are not incorporated into the device as an integral part of the device.

28.6. CMR substances and endocrine-disrupting substances:

The substances are not included in the part (contact part) that may affect the user and patient.

29. Interaction with other substances:

It is not a device which intended to be inserted into the human body and absorbed by the human body or composed of a substance or combination of substances that are localized in the human body.

30. Implantable device:

It is not an implantable device.

31. Warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it:

The housing of X-ray Image Intensifier (I.I.) has lead plate for the prevention of the X-ray leakage. The lead powder or vapor is harmful for human health.

Dispose the scrapped products according to the requirement of local regulation.

32. Use by lay persons:

This device is not intended for use by lay persons.

33. About Article 1(2) of MDR:

This device is not covered by this Regulation pursuant to Article 1(2)

34.Report any serious incident:

If a serious incident occurs in relation to the device, it should be reported to the manufacturer (X-ray system manufacturer) and the competent authority of the Member State in which the user / patient established.

35. IT security measures:

This is not a device that incorporates electronic programmable systems, including software, or software that are devices in themselves.

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Revision History

Rev.	Date	Revised contents
0	2024-04-01	Issued
1	2024-05-16	Add Name and Models

EU IMPORTERS on EU Medical Device Regulation:

Multiple EU IMPORTERs are handling CETD products. For more information about the relations between the CETD products and EU IMPORTERs, please contact CETD.

- **CANON MEDICAL COMPONENTS EUROPE B.V. is the importer which deals CETD products sold via CANON MEDICAL COMPONENTS EUROPE B.V.**

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