



Case File Number: MH-23540-SU-XRE-001

Date of Issue: 21/05/2026

Document Number: 16-DR_SE_AS-103509

Valid Till : 21/05/2031

AUTHORIZATION FOR SUPPLY OF MEDICAL DIAGNOSTIC X-RAY EQUIPMENT

In exercise of the powers conferred under section 16 of the Atomic Energy Act, 1962 read in conjunction with Rule-3 of the Atomic Energy (Radiation Protection) Rules, 2004, the Atomic Energy Regulatory Board (AERB) hereby grants the **Authorization** in favour of **MR. JOHN DAVID KUMAR, ALLANS MEDICAL SYSTEMS PVT. LTD., MUMBAI** hereinafter referred to as the Licensee, for supply of medical diagnostic x-ray equipment, detailed as per Annexure-I.

The **DIRECTOR, ALLANS MEDICAL SYSTEMS PVT. LTD. and MR. JOHN DAVID KUMAR** are hereby identified as the Employer and Licensee respectively, for the purpose of assigning the responsibilities specified in the Atomic Energy (Radiation Protection) Rules, 2004.

The Employer and Licensee are responsible for,

1. Ensuring compliance with the relevant provisions of the
 - i. Atomic Energy Act, 1962
 - ii. Atomic Energy (Radiation Protection) Rules, 2004
 - iii. AERB Safety Code (AERB/SC/Med-2), 2001, Amendment 2012, and the revisions thereof
 - iv. All applicable Safety Codes, Guides issued by AERB for the above practice and regulatory documents issued by AERB from time to time.
 - v. Directives issued by Competent Authority from time to time.
2. Ensuring compliance with terms and conditions stated overleaf.

Note:

This Authorisation is issued ONLY from the RADIATION SAFETY VIEW POINT. All other clearances shall be obtained from concerned state/central/local authorities as applicable.

This Authorization may be suspended, modified or withdrawn as specified in the Atomic Energy (Radiation Protection) Rules, 2004, in the event of contravention of the provisions of the above Act / Rules / Codes or terms and conditions of the Authorization. Where deemed appropriate, AERB may also initiate penal action against the Employer/licensee in such an event.

A copy of this Authorization shall be displayed in a prominent location in the Company premises.

Dr. Pankaj Tandon
Head, RASD

JOHN DAVID KUMAR

ALLANS MEDICAL SYSTEMS PVT. LTD.

NO1 NSS ROAD OPP DATTA MANDIR, NEAR JAMBLI PADA STOP ASLPHA GWHATKOPAR WEST BACK OF DISHA HOPITAL MUMBAI, MAHARASHTRA-400084

Copy to: DIRECTOR, ALLANS MEDICAL SYSTEMS PVT. LTD., MUMBAI

Note: This document is also available at www.aerb.gov.in/elora



परमाणु ऊर्जा नियामक परिषद्, नियामक भवन, अणुशक्तिनगर, मुंबई 400094 (महाराष्ट्र)
Atomic Energy Regulatory Board, Niyamak Bhavan, Anushaktinagar, Mumbai 400094 (Maharashtra)



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Annexure-I

ALLANS MEDICAL SYSTEMS PVT. LTD., MUMBAI is authorized to supply the following models of x-ray equipment:

Type of equipment	Model Name	Manufacturer	Country
Radiography (Fixed)	Allans AXD-100	M/s. Allans Medical Systems	India
Radiography (Mobile)	Allans AXD-100 M	M/s. Allans Medical Systems	India
Radiography (Mobile)	Allans AXD-60	M/s. Allans Medical Systems	India
Dental (Intra Oral)	AX-1070D	M/s. Allans Medical Systems	India
Radiography (Fixed)	AXD-300 R	M/s. Allans Medical Systems	India
Radiography and Fluoroscopy	AXD-300 RF	M/s. Allans Medical Systems	India
Radiography (Fixed)	AXD-500 R	M/s. Allans Medical Systems	India
Radiography and Fluoroscopy	AXD-500 RF	M/s. Allans Medical Systems	India
C-Arm	MENTOR 6R/9R	M/s. Allans Medical Systems	India
Ortho Pantomography (OPG)	XAVIO PG	M/s. Allans Medical Systems	India
Dental (Intra Oral)	AX-1070D	M/s. Allans Medical Systems	India
Radiography (Fixed)	AXD-300	Allans Medical Systems	India
Radiography (Fixed)	AXD-500	Allans Medical Systems	India

Radiography (Mobile)	VECTOR5 HF M	ALLANS MEDICAL SYSTEMS PVT. LTD.	India
Radiography (Fixed)	VECTOR 5HF	ALLANS MEDICAL SYSTEMS PVT. LTD.	India

Note: You are required to apply for 'Modification of Authorization' in case of any change in the details of Annexure-I



TERMS AND CONDITIONS

1. AERB Authorization will be valid for that duration and those models for which OEM authorisation exists.
2. The regulatory responsibilities of the employer, licensee and RSO as laid down in the Atomic Energy (Radiation Protection) Rules, 2004 or the latest revision of AERB Safety Code (AERB/SC/Med-2) shall be adhered to.
3. Availability of qualified and trained personnel and personnel monitoring service to radiation workers shall be ensured all the time.
4. All models of x-ray tube and x-ray tube insert to be imported shall be registered with AERB through eLORA.
5. For procurement/import of x-ray tube(s), the supplier shall obtain procurement permission from the competent authority.
6. The supplier shall supply to the customer only AERB Type approved models and
 - a) on installation of the equipment, shall carry out acceptance testing/quality assurance as part of commissioning of x-ray equipment;
 - b) shall ensure that the customer has the requisite radiation protection devices such as protective barrier, protective apron, couch hanging lead equivalent rubber flaps, ceiling suspended lead equivalent glass etc, as applicable. In case of computed tomography equipment, the supplier shall provide the required phantoms for image quality checks.
 - c) shall check for layout and shielding adequacy at the customer site before installation of x-ray equipment.
 - d) shall submit after every installation, an installation report to the regulatory body in the specified format.
 - e) shall submit confirmation of decommissioning to regulatory body, in case of decommissioning of the x-ray equipment.
7. The Type Approval of the x-ray equipment shall be obtained by any of the OEM authorized suppliers
 - a) Prior to marketing the x-ray equipment the supplier of imported equipment, shall obtain a Type Approval Certificate from the competent authority, on demonstration of performance of the prototype of x-ray equipment.
 - b) Import of prototype of x-ray equipment, meant for Type Approval, shall be carried out by the authorized supplier only after obtaining NOC for import for Type Approval, from the competent authority.
 - c) Subsequent Import of the x-ray equipment after type approval shall be carried out only after obtaining NOC for import from the competent authority.
8. The Annexure-I will require amendment whenever there is any change in the details provided.
9. In case there is change in information specified in this Authorization after its issuance, such as change of Employer, Licensee, name of institution it shall be ensured by licensee that the necessary amendment to this effect to the Authorization is obtained from the Competent Authority.
10. The inventory report in the prescribed format and frequency shall be submitted to AERB.
11. The Authorization shall be renewed before expiry.
12. Full facilities shall be accorded to any authorised inspector of the competent authority to inspect the facility at any time. Records on supply/installation /Type Approvals shall be made available
13. Any incident involving radiation exposure to person shall be intimated to AERB immediately.
14. X-ray equipment shall be supplied only to authorized end-user(s) possessing the requisite procurement permission from AERB and shall be installed at the approved premises.