Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

CERTIFICATE

No. 5Q240612.MSTT91

Certificate's Holder: M/s S S MEDICAL SYSTEMS (INDIA) PVT LTD
Manufacturing Address: F2, Bhimtal Industrial Estate, Bhimtal, DIST. Nainital, Uttarakhand – 263136, INDIA
Registered Address: # C2-43 Safdarjung Development Area, Hauzkhas New Delhi-110016

Certification ECM Mark: Type Approved

Product: Diagnostic Ultrasound Scanner (For Human & Veterinary Use)

Model(s): *(see the following annex)*

Verification to: Standard:
IS 13450(Part-1):2018, IS 13450(Part2/Sec 37):2019,
IEC 60601-1:2005, AMD1:2012,
IEC 60601-2-37:2007+A1:2015, IEC 60601-1-2:2014,
EN ISO 14971:2019, EN 60601-1-6:2010+A1:2015,
IEC 62304:2006/AMD 1:2015, IEC 62366-1:2015+A1:2020,
ISO 13485:2016, MEDDEV 2.7.1 Rev. 4

related to CE Directive(s):
2014/35/EU (Low Voltage)
2014/30/EU (Electromagnetic Compatibility)

Remark:
The manufacturer has voluntarily decided to submit its documents concerning the above-mentioned product for verification. Ente Certificazione Macchine confirms that the documentation made available and immediately returned to it, as containing sensitive data, meets the essential requirements of the above-mentioned directive/standard. The verification activity carried out exclusively concerned the technical documentation and no verification was carried out on the product. This document cannot replace the EC Declaration of Conformity. This document was issued in accordance with regulation RGVOL01 published on the website of www.entecerma.it and concerning voluntary certifications with a non-notified procedure.

Issuance date: 07 June 2024

Expiry date: 06 June 2029

For online check:

S.S. Medical Systems (I) Pvt. Ltd. In Science Since 1941 55000 Installations

Approver
Ente Certificazione Macchine
Legal Representative
Luca Bedonni

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 🖷 +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Annex I

No. 5Q240612.MSTT91

Model(s):

For Human Applications - Iconic Series - SSD 6000 Series -CD PRO, SSD 6000 CD, SSD 6000 CD-E, SSD 6000 CD -EXP, SSD 6000 CD-UST
Magnus Series - DIGI 1100 Series - DIGI 1100 CD PRO, DIGI 1100 CD, DIGI 1100 CD-E, DIGI 1100 CD-AI, DIGI 1100 UST, DIGI 1100 EXP
DIGI 600 Series – DIGI 600 M, DIGI 600 MW, DIGI 600 HYPER 4M, DIGI 600 M PRO, DIGI 600 MBZ, DIGI 600 A PRO, DIGI 6000 A PRO

For Veterinary Applications-Iconic Series-SSD 6000 Series -CD PRO VET, SSD 6000 CD VET, SSD 6000 CD-E VET, SSD 6000 CD -EXP VET, SSD 6000 CD-UST VET
Magnus Series - DIGI 1100 Series - DIGI 1100 CD PRO VET, DIGI 1100 CD VET, DIGI 1100 CD-E VET, DIGI 1100 CD-AI VET, DIGI 1100 UST VET, DIGI 1100 EXP VET
DIGI 600 Series – DIGI 600 M VET, DIGI 600 MW VET, DIGI 600 HYPER 4M VET, DIGI 600 M PRO VET, DIGI 600 MBZ VET, DIGI 600 A PRO VET, DIGI 6000 A PRO VET

S.S. Medical Systems (I) Pvt. Ltd. In Science Since 1941 55000 Installations

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 🖷 +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it

सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2024/000438

1. M/s S.S MEDICAL SYSTEMS (INDIA) PRIVATE LIMITED, MEHRA GAON BHIMTAL NAINITAL UR 263136 INBHIMTAL, Nainital, Uttarakhand (India) - 263136 Telephone No.: 0522 4025395 FAX: 9839022234 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s S. S. Medical Systems (I) Pvt Ltd, 220 Bhopal House, Lalbagh,, Lucknow, Uttar Pradesh (India) - 226001 Telephone No.: 7718022219 FAX: 9022917032

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Ultrasound Imaging Machine Model No.:DIGI 1100 CD E - High Resolution 15.6 LED Supports JPG BMP FRM image formats and CIN AVI WMV movie format,DIGI 1100 CD PRO - Laptop design Color Doppler with 15.6 inch high resolution medical grade LCD monitor Supports JPG BMP FRM image formats and CIN AVI WMV movie format,DIGI 1100 CD - Laptop design Colour Doppler with 15.6 inch high resolution medical grade LCD monitor Supports JPG BMP FRM image formats and CIN AVI WMV movie format,SSD 6000 CD E - 15 to 19 inch customizeable Monitor size 8 step zoom magnification with PAN facility,SSD 6000 CD PRO - 21.5 inch 1920x1080 high resolution LCD monitor with tilt & swivel facility Supports JPG BMP FRM image formats and CIN AVI movie formats,SSD 6000 CD - 19 inch high resolution LCD monitor with tilt and swivel facility Supports JPG BMP FRM image formats and CIN AVI movie format Intended Use:The device is intended for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Abdominal, Fetal/Obstetric, Gynaecological, Fetal Echo, Musculo-skeletal (conventional), Urology and Paediatric. Class of medical device:Class B Material of construction:PCB, FRP, LCD, Control Board Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SSMED

Place: Lucknow

Date 25-Jun-24

S.S. Medical Systems (I) Pvt. Ltd. In Science Since 1941 55000 Installations

(Shashi Mohan Gupta)
Drug Licensing and Controlling Authority
Uttar Pradesh
State Licensing Authority

CERTIFICATE OF COMPLIANCE

INTERNATIONAL CERTIFICATION SERVICES PVT. LTD.

This is to certify that the
QUALITY MANAGEMENT SYSTEM of

S S MEDICAL SYSTEMS (INDIA) PRIVATE LIMITED

Corporate Address: 5 Park Road, Ground Floor, Thapar House, Opposite Civil Hospital Emergency Gate No. 2, Hazratganj, Lucknow – 226001 Uttar Pradesh, India.
Regd. Address: - F2, Industrial Estate, Bhimtal, Nainital, Uttarakhand-263136, India.
Site 1: - 220 Bhopal House, Lalbagh, Lucknow, Uttar Pradesh, 226001, India.
Site 2:- 707, 7th floor, Ansal bhawan, Kasturba Gandhi Marg, Barakhamba Road, New Delhi – 110001, India.

has been assessed and registered as complying with the requirements of the following International Standard:

ISO 13485 : 2016

The Quality Management System for Medical Devices applicable to :

Scope : **Manufacturing, Sales & Services of Medical Devices Such as Ultrasounds & Colour Doppler Machines, Multipara Patient Monitoring System, Pulse Oximeters, ECG, Infusion Pumps, Oxygen Concentrators and Hospital Furniture Such as Hospital Ward Furniture's, O.T. Tables, O.T. Lights, Defibrillator Machine.**

Registration No.	**: RQMD91/11245**
Registered Date	**: 26th September, 2022**
Issue Date	**: 27th September, 2022**
Expiry Date	**: 25th September, 2025**

QMS 009

RED
Invalid After
09/09/2023
Unless
Hologram
Pasted

S.S. Medical Systems (I) Pvt. Ltd.
In Science
Since 1941
55000 Installations

Managing Director
International Certification Services Pvt. Ltd.

Accredited by National Accreditation Board For Certification Bodies, India.

Validity of this certificate is based on periodic audits of the management system defined by the above scope and is contingent upon prompt, written notification of significant changes to the management system and/or its components thereof shall be immediately communicated to ICS.
Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained at www.icsasian.com/ www.icspl.org

Certificate of Registration

This is to certify that the

Quality Management System

of

S S MEDICAL SYSTEMS (INDIA) PVT. LTD.

at

F2 & F13, BHIMTAL INDUSTRIAL ESTATE, BHIMTAL, DIST. NAINITAL, UTTARAKHAND – 263136, INDIA

has been independently assessed and is compliant with the requirements of:

ISO 9001:2015

For the following scope of activities:

MANUFACTURER AND SUPPLY OF ULTRASOUNDS, COLOUR DOPPLERS, PATIENT MONITORS, ECG MACHINE, INFUSION PUMPS, MEDICAL AND HOSPITAL FURNITURE, HEMATOLOGY ANALYZER BIO-CHEMISTRY ANALYZER, ELISA READER & WASHER OXYGEN CONCENTRATOR, BIO MEDICAL WASTE CONSUMABLES & DISPOSAL EQUIPMENT, CBWTF EQUIPMENT, MOBILE MEDICAL UNITS (MMU), MICROWAVE MEDICAL WASTE DISINFECTION & STERILIZATION SYSTEM, CARDIAC MONITOR WITH DEFIBRILLATOR, AUTOMATIC ELECTRONICS DEFIBRILLATOR (AED) & LABORATORY LIQUID WASTE TREATMENT EQUIPMENT AND ALL THE ABOVE PRODUCTS ARE FOR HUMAN & FINALIZE AS WELL AS VETERINARY USE

Certificate Number: UQ - 20230127104

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of initial registration	27th January 2023
Date of this Certificate	27th January 2023
Certificate Expiry	26th January 2026
Recertification Due	26th January 2026

Authorised Signatory

ISO 13485:2016

Scan this code with your smart phone to verify the certificate

Certificate of Registration

This is to certify that the Quality Management System of

S S MEDICAL SYSTEMS (INDIA) PRIVATE LIMITED

F2, BHIMTAL INDUSTRIAL ESTATE, BHIMTAL, DISTT. NANITAL, UTTARAKHAND-263136, INDIA

has been assessed by PQC and found to comply with the requirements of

ICMED 13485:2016 Plus Scheme

(Indian Certification for Medical Devices-Quality Management System)

For the following scope:

MANUFACTURE AND SUPPLY OF ULTRASOUNDS, COLOUR DOPPLERS, PATIENT MONITORS, ECG MACHINE, INFUSION PUMPS, CARDIAC MONITOR WITH DEFIBRILLATORS, AUTOMATIC ELECTRONICS DEFIBRILLATOR (AED), MEDICAL AND HOSPITAL FURNITURE, PATHOLOGY EQUIPMENTS, BIO MEDICAL WASTE CONSUMABLES, MICROWAVE MEDICAL WASTE DISINFECTION & STERILIZATION SYSTEM, LABORATORY LIQUID WASTE TREATMENT EQUIPMENT. ALL THE ABOVE PRODUCTS ARE FOR HUMAN & FINALIZE AS WELL AS VETERINARY USE

COMPLIES WITH THE REQUIREMENTS APPLICABLE TO IT

The Certification Body has performed an audit of the above product quality system covering the manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the ICMED. This Certificate will be valid while client is maintaining all the documents & its implementation, testing etc. w.r.t. ICMED.

Certification Calendar:

Client Id: 43085

Certificate No: INMD/UK-44958/1223

Initial Registered Date: 23.12.2023 Issuance Date: 23.12.2023

Date of Expiry: 22.12.2026

1st Surv. Due: 22.12.2024 2nd Surv. Due: 22.12.2025

ACCREDITED
Management System Certification

Authorized Signatory

PARAMOUNT QUALITY CERTIFICATIONS

27, Old Gloucester Street, London, WC1N 3AX, United Kingdom. Email:- info@pqcert.in

Validity of this certificate is subject to successful completion of surveillance audit on or before of due date.
(In case surveillance audit is not allowed to be conducted, this certificate shall be suspended/withdrawal.)
Certification Verification: Please check this validity of the certificate at:- https://pqcert.in/certified-clients/ or www.pqcert.in at Certified Client
This Certificate remains the property of PQC & shall be returned immediately upon request.

www.pqcert.in

ISO 9001:2015

Scan this code with your smart phone to verify the certificate

Certificate of Registration

This is to certify that the Quality Management System of

S S MEDICAL SYSTEMS (INDIA) PRIVATE LIMITED

F2 BHIMTAL INDUSTRIAL ESTATE, BHIMTAL, DISTT. NANITAL, UTTARAKHAND-263136, INDIA

has been independently assessed by PQC and found to comply with the requirements of

ICMED 9001:2015

(Indian Certification for Quality Management System)

Certification Scope:

MANUFACTURE AND SUPPLY OF ULTRASOUNDS, COLOUR DOPPLERS, PATIENT MONITORS, ECG MACHINE, INFUSION PUMPS, CARDIAC MONITOR WITH DEFIBRILLATORS, AUTOMATIC ELECTRONICS DEFIBRILLATOR (AED), MEDICAL AND HOSPITAL FURNITURE, PATHOLOGY EQUIPMENTS, BIO MEDICAL WASTE CONSUMABLES, MICROWAVE MEDICAL WASTE DISINFECTION & STERILIZATION SYSTEM, LABORATORY LIQUID WASTE TREATMENT EQUIPMENT. ALL THE ABOVE PRODUCTS ARE FOR HUMAN & FINALIZE AS WELL AS VETERINARY USE.

COMPLIES WITH THE REQUIREMENTS APPLICABLE TO IT:

The Certification Body has performed an audit of the above product quality system covering the manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the ICMED. This Certificate will be valid while client is maintaining all the documents & its implementation, testing etc. w.r.t. ICMED.

Certification Calendar:

Client Id: 43085

Certificate No: INQ/UK-44959/1223

Initial Registered Date: 23.12.2023 Issuance Date: 23.12.2023

Date of Expiry: 22.12.2026

1st Surv. Due: 22.12.2024 2nd Surv. Due: 22.12.2025

SCOTLAND Accredited Services Limited
ACCREDITED
Management System Certification

CERTIFIED ISO 9001:2015 CERTIFIED

Medical Systems (I) Pvt. Ltd. In Science Since 1941 3000+ Installations

Authorized Signatory

PARAMOUNT QUALITY CERTIFICATIONS

27, Old Gloucester Street, London, WC1N 3AX, United Kingdom. Email:- info@pqcert.in

Validity of this certificate is subject to successful completion of surveillance audit on or before of due date.

(In case surveillance audit is not allowed to be conducted, this certificate shall be suspended/withdrawal.)

Certification Verification: Please check this validity of the certificate at:- https://pqcert.in/certified-clients/ or www.pqcert.in at Certified Client

This Certificate remains the property of PQC & shall be returned immediately upon request.

www.pqcert.in

PQC SCT

Certificate of Compliance

Certificate Number: UQ-2022052099

This is to certify that

S S MEDICAL SYSTEMS (INDIA) PVT. LTD.

at

F2, BHIMTAL INDUSTRIAL ESTATE, BHIMTAL, DIST. NAINITAL, UTTARAKHAND – 263136, INDIA

Has successfully implemented the Quality management System and been found working satisfactorily as per the norms of **"Good Manufacturing Practice"** as laid down by "**World Health Organisation** "which has been in conformance to the requirements of

WHO-GMP

Scope: **MANUFACTURER AND SUPPLY OF ULTRASOUNDS, COLOUR DOPPLERS, PATIENT MONITORS, ECG MACHINE, INFUSION PUMPS, MEDICAL AND HOSPITAL FURNITURE, HEMATOLOGY ANALYZER BIO-CHEMISTRY ANALYZER, ELISA READER & WASHER OXYGEN CONCENTRATOR, BIO MEDICAL WASTE CONSUMABLES & DISPOSAL EQUIPMENT, CBWTF EQUIPMENT, MOBILE MEDICAL UNITS (MMU), MICROWAVE MEDICAL WASTE DISINFECTION & STERILIZATION SYSTEM, CARDIAC MONITOR WITH DEFIBRILLATOR, AUTOMATIC ELECTRONICS DEFIBRILLATOR (AED), LABORATORY EFFLUENT TREATMENT PLANT (LAB-ETP), LABORATORY EFFLUENT TREATMENT PLANT (LAB ETP) WITH DISINFECTANT GENERATION SYSTEM & MODULAR HOSPITAL EFFLUENT TREATMENT PLANT. ALL THE ABOVE PRODUCTS ARE FOR HUMAN & FINALIZE AS WELL AS VETERINARY USE**

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced Models Products.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed and is subject to continuous surveillance according to the WHO-GMP Guidelines
3. The certificate validity is conditioned by positive results or surveillance audits.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of initial Registration	20th May 2022
Date of this Certificate	20th May 2022
Certificate Expiry	19th May 2025
Recertification Due (subject to the company maintaining its system to the required standard)	19th May 2025

Authorised Signatory

Certificate of Registration

This is to certify that the

Environmental Management System

of

S S MEDICAL SYSTEMS (INDIA) PVT. LTD.

at

F2 & F13, BHIMTAL INDUSTRIAL ESTATE, BHIMTAL, DIST. NAINITAL, UTTARAKHAND – 263136, INDIA

has been independently assessed and is compliant with the requirements of:

ISO 14001:2015

For the following scope of activities:

MANUFACTURER AND SUPPLY OF ULTRASOUNDS, COLOUR DOPPLERS, PATIENT MONITORS, ECG MACHINE, INFUSION PUMPS, MEDICAL AND HOSPITAL FURNITURE, HEMATOLOGY ANALYZER BIO-CHEMISTRY ANALYZER, ELISA READER & WASHER OXYGEN CONCENTRATOR, BIO MEDICAL WASTE CONSUMABLES & DISPOSAL EQUIPMENT, CBWTF EQUIPMENT, MOBILE MEDICAL UNITS (MMU), MICROWAVE MEDICAL WASTE DISINFECTION & STERILIZATION SYSTEM, CARDIAC MONITOR WITH DEFIBRILLATOR, AUTOMATIC EXTERNAL DEFIBRILLATOR (AED) & LABORATORY LIQUID WASTE TREATMENT EQUIPMENT, VENTILATORS APPLICABLE FOR BOTH HUMAN & VETERINARY USE

Certificate Number: UQ - 2023062079

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	20th June 2023
1st Surveillance Audit Due	19th June 2024
2nd Surveillance Audit Due	18th June 2025
Certificate Expiry	19th June 2026

Authorised Signatory

S.S. Medical Systems (I) Pvt. Ltd. In Science Since 1941 35000 Installations UKAF

UK Certification & Inspection Ltd.

Certificate of Compliance

Standard Compliance

We hereby declare that the technical file of product confirms with the requirement of **IEC 80601-2-49:2018.**

Certificate No.: UQ-2023121101

Manufacturer

Name : **SS MEDICAL SYSTEMS (INDIA) PRIVATE LIMITED**

Address : **F2 & F13, BHIMTAL INDUSTRIAL ESTATE, BHIMTAL, DIST. NAINITAL, UTTARAKHAND-263136, INDIA**

Products : **Ultrasounds, Colour Dopplers, Patient Monitors, ECG Machine Infusion Pumps, Medical and Hospital Furniture Pathology Equipments, Bio Medical Waste Consumables & Microwave Medical Waste Disinfection & Sterilization System, All The Above Products Are for Human & Finalize as Well as Veterinary Use, Laboratory Liquid Waste Treatment Equipment**

The Certification body has performed an audit of the above product testing and verified the design system, manufacture and final inspection of the certified product. The product specification has been assessed, approved and is subject to continuous surveillance according to Standard **IEC 80601-2-49:2018** requirement.

This certificate is issued under the following conditions:

1. Fulfilled are requirement as per implemented of suggested standards
2. The certificate remains valid until the manufacturing conditions are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant Standard testing performance, the manufacturer shall affix to each device, of the referenced models.

The compliance as shown above can be used, under the responsibility of the manufacturer, after completion of a Declaration of conformity and compliance with all relevant Standard requirements. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	11th December 2023
1st Surveillance Audit Due	10th December 2024
2nd Surveillance Audit Due	10th December 2025
Certificate Expiry (subject to the company maintaining its system to the required standard)	10th December 2026

S.S. Medical Systems (I) Pvt. Ltd. In Science Since 1941 50000+ Installations

UK Certification & Inspection Ltd.

Authorised Signatory

Certificate

We hereby declare that the technical file of product complied with the requirement of directives 93/42/EEC Medical Device Directive and IEC Standard requirements.

Certificate No.: UQ-2023062078

Manufacturer

Name : **S S MEDICAL SYSTEMS (INDIA) PVT. LTD.**

Address : **F2, Bhimtal Industrial Estate, Bhimtal, Dist. Nainital, Uttarakhand – 263136, India**

Product : **Medical Electrical Equipments Covered Under CE certificate No. CE-3019**

Applicable standards: IEC 60601

MEDICAL ELECTRICAL EQUIPMENT
PART-I: GENERAL REQUIREMENT OF
SAFETY FOR ELECTROMAGNETIC COMPATIBIILTY;
PART-2: GENERAL REQUIREMENT OF ELECTRICAL SAFETY.
Covering the standards as per Annexure-1, (page 1 & 2)

Complies with the requirements applicable to it

The manufacturer's technical documentation as required has been reviewed and found to comply with the requirements. Any significant changes in the design or construction of the product, not agreed upon by us, this declaration will lose its validity.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of Equipments & Models covered under CE certificate No. CE-3019 and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions with applicable EN requirement or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits annually.
4. After fulfilling the relevant IEC legislations and IEC Requirements, the manufacturer shall affix to each device, of the referenced models.
5. The IEC Certificate as shown above can be used, under the responsibility of the manufacturer, after completion of an IEC Declaration of conformity and compliance with all relevant IEC Directives. The statement is based on a single evaluation of one random sample of above mentioned products. It does not imply an assessment of the whole production

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	20th June 2023
1st Surveillance Audit Due	19th June 2024
2nd Surveillance Audit Due	19th June 2025
Certificate Expiry (subject to the company maintaining its system to the required standard)	19th June 2026

S.S. Medical Systems (I) Pvt. Ltd. In Science Since 1941 5000+ Installations

UK Certification & Inspection Ltd.

Authorised Signatory

ANNEXURE -1 **Certificate No. UQ-2023062078**

Standard:	Title:
IEC 60601-1	Medical Electrical Equipment -Part 1: General Requirements for Basic safety and Essential Performance
IEC 60601-1-1	Medical Electrical Equipment -Part 1-1: General Requirements for safety- Collateral standard: Safety requirements for medical electrical system
IEC 60601-1-2	Medical Electrical Equipment -Part 1-2: General Requirements for Safety- Collateral standard : Electromagnetic Compatibility- Requirements and tests (Tested for comprehensive standard IEC 60601-1-2:1993 1st Edition, IEC 60601-1-2:2001 2nd Edition consolidated with amendment 1:2004, consolidated with amendment 1:2020)
IEC 60601-1-4	Medical Electrical Equipment -Part 1-4: General Requirements for Safety-Collateral Standard: Programmable electrical medical system
IEC 60601-1-6	Medical Electrical Equipment -Part 1-6: General Requirements for basic safety and essential performance-Collateral standard:
IEC 60601-1-8	Medical Electrical Equipment -Part 1-8: General Requirements for basic safety and essential performance-Collateral standard: General requirements, tests and guidance for alarm system in medical electrical equipment and medical electrical system
IEC 60601-1-9	Medical Electrical Equipment -Part 1-9: General Requirements for basic safety and essential performance-Collateral Standard: Requirements for environmentally conscious design
IEC 60601-1-11	Medical Electrical Equipment -Part 1-11: General Requirements for basic safety and essential performance-Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-2-1	medical electrical equipment-Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 Mev
IEC 60601-2-4	Medical electrical equipment-Part 2-4:Particular requirements for the safety of cardiac defibrillators
IEC 60601-2-10	Medical electrical equipment-Part 2:Particular requirements for the safety of nerve and muscle stimulators
Amendment 1 For IEC 60601-2-10	Amendment 1 for Medical electrical equipment - Part 2: Particular requirements for the safety of nerve and muscle stimulators

Authorised Signatory

ANNEXURE -1 **Certificate No. UQ-2023062078**

Standard:	Title:
IEC 60601-2-12	Medical electrical equipments - part 2-12: particular requirements for the safety of lung ventilators-Critical care ventilators
IEC 60601-2-13	Medical electrical equipments - part 2-13: particular requirements for the safety and essential performance of anaesthetic systems
IEC 60601-2-18	Medical electrical equipments - part 2-18: particular requirements for the basic safety and essential performance of endoscope equipment
IEC 60601-2-19	Medical electrical equipments - part 2-19: particular requirements for the basic safety and essential performance of infant incubators
IEC 60601-2-20	Medical electrical equipments - part 2-20: particular requirements for the basic safety and essential performance of infant transport incubators
IEC 60601-2-21	Medical electrical equipments - part 2-21: particular requirements for the basic safety and essential performance of infant radiant warmers
IEC 60601-2-23	Medical electrical equipments - part 2-23: particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment
IEC 60601-2-24	Medical electrical equipments - part 2-24: particular requirements for the safety of infusion pumps and controllers
IEC 60601-2-25	Medical electrical equipments - part 2: particular requirements for the safety of electrocardiographs
IEC 60601-2-27	Medical electrical equipments - part 2-27: particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
IEC 60601-2-34	Medical electrical equipments - part 2-34: particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment
IEC 60601-2-37	Medical electrical equipments - part 2-37: particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-46	Medical electrical equipments - part 2-46: particular requirements for the safety of operating tables

In Science Since 1941

Authorised Signatory

ANNEXURE -1 **Certificate No. UQ-2023062078**

Standard:	**Title:**
IEC 60601-2-47	Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
IEC 60601-2-49	Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
IEC 60601-2-50	Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment
IEC 60601-2-51	Medical electrical equipment - Part 2-51: particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs
IEC 60601-2-52	Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds

Certificate History

-:

Revision	Date	Reference Number	Action
	2020-07-04	UQ-2023062078	Certification
a	2020-12-15	UQ-2023062078 (a)	Tested for comprehensive standard IEC 60601-1-2:1993 1st Edition , IEC60601-1-2:2001 2nd Edition consolidated with amendment 1:2004 3rd Edition consolidated with amendment 1:2020

Date :15-06-2023

Authorised Signatory