



CERTIFICATE

This is to certify that the product listed below conforms to the requirements of the

Directives Name Medical Devices (MDD) Directive 93/42/EEC
Medical Device Regulation (MDR) (2017/745)

Certificate no.: IN9461U-2022 **Date of Expiry:** 10 February 2025

Date of Initial Reg.: 11 February 2022 **Surv. Date :** 10 February 2025

Date of Issue: 11 February 2022

Manufacturer : **ELESONIC HEALTHCARE PVT. LTD.**

SAHEBAN BAGICHA, NODAKHALI, P.O.-MUCHISA, BAKHRAHAT,
24 PGS (SOUTH) PIN. - 743377, WEST BENGAL, INDIA

Description of Products :

- 1) Elemac 50 - 50ma / 85 Kvp Protoble Diagnostic X-Ray Machine
- 2) Elemac 100 M - 100ma / 100 Kvp Mobile Diagnostic X-Ray Machine Machine.
- 3) Elemac 100 - 100ma / 100 Kvp Static Diagnostic X-Ray Machine with Bucky X-Ray Table.
- 4) Elemac 300- 300ma / 125 Kvp Floor Mounted Diagnostic X-Ray Machine with Floating Bucky X-Ray Table.
- 5) Elemac 500- 500ma / 125 Kvp Floor Mounted Diagnostic X-Ray Machine with Floating Bucky X-Ray Table.
- 6) Elemac CII - C-Arm Mobile Image Intensifier 9" Dia.

Equipment Identification : As Shown of Above

Other Certification : NA

Standards Applied : As Required

Report Reference: EHPL/IN9461U-2022

This Report has been Issued by Certiva Limited according to the provision of the **Medical Devices (MDD) Directive 93/42/EEC**
This Report is issued following the assessment of the documentation and implementation of the Quality System in accordance with the provisions of the quoted Conformity Assessment Module of the above directives.
The CE Mark may be affixed to the press **Medical Devices (MDD) Directive 93/42/EEC**
the Scope of approvals as described above once the 'EU declaration of conformity' has been signed by the responsible person.




Director



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