



Certificate of Compliance

This is to Certify that the following designated products :

Annexure-I

This certificate is issued under the following conditions:

1. It applies only to the above referenced set of products mentioned above. The manufacturer is obligated to assure that all products of the respective model confirm to the type assessed by this certificate
2. The Certificate validity is conditioned by the positive result of the surveillance audits.
3. The Certificate remains valid until the manufacturing conditions, the quality systems or relevant legislation are changed but until the 05/03/2023
4. After Fulfilling the EU legislation requirements, the manufacturer shall affix to each product of the above referenced models, CE Marking according to the following example

Manufactured By

X-Tech Medical Systems Private Limited

P-434, PARNASREE PALLY, KOLKATA, Kolkata, West Bengal- 700060
Factory: Nandipukur More, Near Adisaptagram Railway Level Crossing,
PO - Addconagar. PS Mogra, Hooghly , WB, -712121, India

*Conforms with the Applicable requirements of
Medical Device Directive (93/42/EEC)*

CERTIFICATE NO. : 20ZEZK3858C

ISSUED DATE : 06/03/2020
EXPIRY DATE : 05/03/2023

1ST SURVEILLANCE : 05/03/2021
2ND SURVEILLANCE : 05/03/2022



Authorised Signatory

INTERNATIONAL QUALITY CERTIFICATION SERVICES UK LTD



544302





Certificate of Compliance

Manufactured By :

X-Tech Medical Systems Private Limited

Product Details

- 1- Mobile Diagnostic Medical X - Ray Equipment Line
Frequency - 100mA.
- 2- Stationery Diagnostic Medical X-Ray Equipment
Line Frequency - 100mA, 300mA, 500mA, .
- 3- Mobile Diagnostic Medical X-Ray Equipment High
Frequency - 2.5kW, 3.5kW, 4.2kW, 6kW, 15kW, 24kW, 32kW, 40kW.
- 4- Stationery Diagnostic Medical X-Ray Equipment
High Frequency - 2.5kW, 3.5kW, 4.2kW, 6kW, 15kW,
24kW, 32kW, 40kW, 50kW, 80kW.
- 5- Mobile C-ARM - 3.5kW, 5kW.

Annexure-I Certificate No:-20ZEZK3858C



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