REGAL QUALITY REGISTRARS INC.

CERTIFICATE

Certificate of Compliance

We confirm that the technical documentation for the below mentioned products according 93/42/EEC (MDD)

Products:
LED X RAY VIEWER : SINGLE SCREEN
DUAL SCREEN
TRIPLE SCREEN
QUADRUPLE SCREEN

SURGEON CONTROL PANEL
PATIENT MONITOR

Manufactured by company:

Bio- X
Office Add: 5th Floor, Span Center South Avenue, Santacruz West, Mumbai- 400054, Maharashtra, India
Factory Add: J-31, MIDC Taloja, District Raighad, Maharastra - 410208, India

is complying to the applicable essential requirements of 93/42/EEC Medical Devices Directive (MDD)
The Regal Quality Registrars Inc. has conducted with successful results the review of the manufacturer's technical documentation of the certified according to above mentioned Directive.
This certificate is issued under the following conditions:
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.

1. The Certificate validity is conditioned by the positive results of the surveillance audits.
2. The Certificate remains valid until the manufacturing conditions, the quality systems or relevant legislation are changed but until the 29th November 2019.
3. After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each product of the above referenced models, CE Marking according to the following example.

Certificate No. : CE-2523
Date of registration : 30th Nov 2016
Date of this certificate: 30th Nov 2016
Date of Expiry : 29th Nov 2019

CE

Authorized Signatory
Regal Quality Registrars Inc.

Statement:
This certificate of conformity based on the evaluation of a sample of the above mentioned products. It does not imply an assessment of the mass-production of the product. The certification body should be informed (revision of technical file) for any modification or alterations made to the aforementioned product type(s). The manufacturer is responsible for the product and ensuring that all manufactured products are in compliance with the specifications declared in the technical construction file.
Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by contacting the organization. Check www.regalregistrars.co.uk for current status of the certificate. Whilst all due care and skill was exercised in carrying out this assessment, RQRI accepts responsibility only for proven gross negligence. This certificate remains property of RQRI to whom it must be returned upon request.