Certificate of Compliance

CE

We hereby declare that the technical file of product complied with the requirements of EC directive 93/42/EEC Medical Device Directive (MDD).

Certificate No.: CE- 58423

Manufacturer

Name : **MDX INSTRUMENTS CO. INC**

Address : **Central Lane, Bridgeport, Connecticut - USA 06605**

Products : Intensive Care Products, Medical Imaging, Infant Care Products Rehabilityation Products, Diagnostic Products, ENT Products Gynae Products, Monitoring Devices, Infusion Devices etc.

Models : See Appendix

Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC class I.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are not changed.
3. The certificate validity is conditioned by positive results of surveillance audits.
4. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. 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.

Date of Certification	24th April 2024
1st Surveillance Audit Due	24th April 2025
2nd Surveillance Audit Due	24th April 2026
Certificate Expiry (subject to the company maintaining its system to the required standard)	23rd April 2027

Authorised Signatory

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Company No. 11847851