Certification & Inspection

Certificate of Compliance

CE

We hereby declare that the technical file of product class 1 complied with the requirement of the Medical Council Directives 93/42/EEC of June 1993.

Certificate No.: CE-25618

Manufacturer

Name : MDX Instruments Co. Inc

Address : Central Lane, Bridgeport - Connecticut, USA 06605

Products : **Design and Manufacture of Lab & Medical Devices**

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to the directive Medical Council Directives 93/42/EEC of June 1993 of class 1.

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 changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant EU legislation of Class 1 in medical directive, the manufacturer shall affix to each device, of the referenced models.
5. 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 in Class 1 product. The statement is based on a single evaluation of one sample of above mentioned products. It does not imply an assessment of the whole production.

Date of initial registration	24th April 2018
Date of this certificate	24th April 2020
Certificate expiry	23rd April 2023
Recertification due (subject to the company maintaining its system to the required standard)	23rd April 2024

Authorised Signatory

UK Certification & Inspection Ltd.

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