EC Certificate Production Quality Assurance System: Certificate GB11/84488

The management system of

MD Diagnostics Ltd

15 Hollingworth Court, Turkey Mill, Ashford Road, Maidstone, Kent, ME14 5PP, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Breath Monitor for detection of Carbon Monoxide used in the treatment for Smoking Cessation and CO poisoning
Handheld respiratory pressure meter for measuring mouth and nasal pressures
Disposable Respiratory Mouth Piece (with or without bacterial/viral filter) and Reusable Mouthpiece adaptor including a one-way valve for use with respiratory breath monitors.

Annex V Metrological aspects only - Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements
Hydrogen Breath Monitor to aid diagnosis of lactose Intolerance.

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 28 November 2019 until 20 December 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 16 November 2020
Issue 10. Certified since 20 December 2011

Certification is based on reports numbered GB/PC 227543

Authorised by

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