

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Waters Technologies (Ireland) Ltd  
Wexford Business Park  
Drinagh  
Wexford  
Y35 D431  
Ireland

Holds Certificate Number:

**MD 739855**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development and manufacture of in-vitro diagnostic kits, reagents, calibrators, controls and accessories. Manufacture of High-Performance Liquid Chromatography (HPLC) and Mass Spectrometry (MS), Chromatographic products and the associated replication and packaging of application software for In Vitro Diagnostic use.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-05-20

Latest Revision Date: 2022-12-05

Effective Date: 2023-02-01

Expiry Date: 2026-01-31

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