# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

Mologic Ltd
Bedford Technology Park
Thurleigh
Bedford
MK44 2YA
United Kingdom

DUNS Number: 73-521-6140

Holds certificate No: **MDSAP 676231**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Canada - Medical Devices Regulations - Part 1- SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

Design, development and manufacture of professional and self-test immunodiagnostic (lateral flow) IVD devices for the detection of infectious disease, inflammatory biomarkers and human Chorionic Gonadotropin (hCG).

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2018-12-06 Effective Date: 2018-12-06 Expiry date: 2021-09-24



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