

# EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

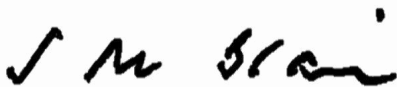
**No.** CE 654083  
**Issued To:** **Mologic Ltd**  
**Bedford Technology Park**  
**Thurleigh**  
**Bedford**  
**MK44 2YA**  
**United Kingdom**

In respect of:

**Development and manufacture of self-test in vitro diagnostic devices for the detection of markers of infectious and inflammatory disease status, as an aid to diagnosis, using immunochromatographic (e.g. lateral flow strip) technology.**

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2017-02-07**

Date: **2018-02-22**

Expiry Date: **2022-02-06**

...making excellence a habit.™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Certificate - Full Quality Assurance Certificate History

**Certificate No:** CE 654083  
**Date:** 2018-02-22  
**Issued To:** **Mologic Ltd**  
**Bedford Technology Park**  
**Thurleigh**  
**Bedford**  
**MK44 2YA**  
**United Kingdom**

Date	Reference Number	Action
07 February 2017	8533330	First Issue.
Current	8890420	Change to Postcode in address from MK44 2YP to MK44 2YA.

...making excellence a habit.™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

This certificate was issued electronically and is bound by the conditions of the contract.