

Certificate of Management System

Eurofins E&E CML Limited, Newport Business Park, New Port Road, Ellesmere Port
CH65 4LZ, UK, accredited by the United Kingdom Accreditation Service (UKAS),
registration number 8175, certifies that the Quality Management System of

Caltag Medsystems Ltd

Whiteleaf Business Centre,
11 Little Balmer,
Buckingham.
MK18 1TF

Has been assessed and found to comply with the requirements of

EN ISO 13485:2016

The scope of this certification extends to the following:

Design, development and manufacture of cellular stabilisation reagents for in vitro diagnostic use. Distribution of in vitro diagnostic kits and reagents. Control of manufacture and distribution of cellular stabilisation reagents for in vitro diagnostic use.

Certificate Number CML QMSMDY2709

Issue Number 4

Initial issue date 27th July 2023

Current issue 29th July 2025

Expiry 6th August 2028

Period out of scope:

7th August 2022 to 27th July
2023 was covered by another
certification body



8175



eurofins



Certification Schedule

Location	Activities
Cytomark Ltd Whiteleaf Business Centre, 11 Little Balmer, Buckingham, MK18 1TF, United Kingdom	ISO 13485:2016 Control of manufacture and distribution of cellular stabilisation reagents for in vitro diagnostic use.
Caltag Medsystems Ltd Whiteleaf Business Centre, 11 Little Balmer, Buckingham, MK18 1TF, United Kingdom	ISO 13485:2016 Design, development, and manufacture of cellular stabilisation reagents for in vitro diagnostic use. Distribution of in vitro diagnostic kits and reagents.