7 August 2022 6 August 2025 10460723 Original approval(s): ISO 13485 - 7 August 2013

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Certificate of Approval

This is to certify that the Management System of:

Caltag Medsystems Ltd

Whiteleaf Business Centre, 11 Little Balmer, Buckingham, MK18 1TF, United Kingdom

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 - 00004605

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

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.

David Denn

David Derrick

Area Operations Manager UK & Ireland

Issued by: LRQA Limited



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Issued by: LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom



Certificate identity number: 10460723

Certificate 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.

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