

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

CellaVision AB  
Mobilvägen 12  
SE-223 62 Lund  
Sweden

Holds Certificate Number:

MD 783061

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

The Design, Manufacture, Distribution, Installation and Servicing of in-vitro diagnostic instruments and software for analysis of blood, other body fluids and tissues.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2023-01-11

Latest Revision Date: 2025-04-09

Effective Date: 2025-07-12

Expiry Date: 2028-07-11

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