

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

CellaVision AB  
Mobilvägen 12  
Lund  
SE-223 62  
Sweden

Facility ID Number: F000119

Holds Certificate No:

**MDSAP 691622**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

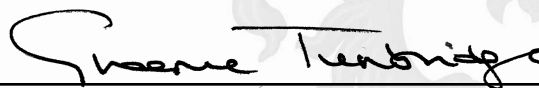
**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

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: 2019-08-09

Effective Date: 2025-07-12

Expiry Date: 2028-07-11



BSI Group America Inc. is an MDSAP recognised auditing organization

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