EU DECLARATION OF CONFORMITY

Manufacturer	CellaVision AB Mobilvägen 12 SE-223 62 LUND SWEDEN
Single registration no.	SE-MF-000002377
Products	CellaVision® DC-1 and DC-1 PPA including accessories, medical device software and associated software products pertinent to the device, see table below
IVDR classification	A
IVDR Conformity assessment procedure	Annex XI of (EU) 2017/746 of the European Parliament

Intended use of the CellaVision® DC-1
The CellaVision® DC-1 is an automated cell-locating device intended for in-vitro diagnostic use in clinical laboratories. The CellaVision® DC-1 is intended to be used by operators, trained in the use of the device.

Intended use of the CellaVision Peripheral Blood Application
The CellaVision Peripheral Blood Application is intended for differential count of white blood cells (WBC), characterization of red blood cell (RBC) morphology and platelet estimation.

The CellaVision® DC-1 with the CellaVision Peripheral Blood Application automatically locates blood cells on peripheral blood smears. The application presents images of the blood cells for review. A skilled operator trained in recognition of blood cells, identifies and verifies the suggested classification of each cell according to type.

IVDR (EU) 2017/746
CellaVision AB hereby declares, under our sole responsibility, that the device described above complies with Regulation (EU) 2017/746 of the European Parliament and of the Council of 05 April 2017.

Machinery Directive 2006/42/EC
CellaVision AB hereby declares, under our sole responsibility, that the device described above complies with applicable parts of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 and its transposition into national laws on relevant markets.

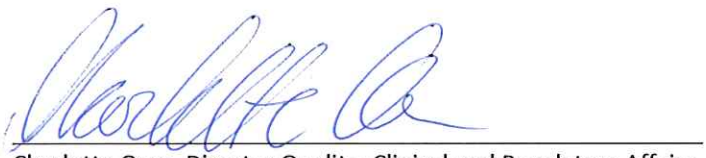
RoHS Directive 2011/65/EU and amendment (EU) 2015/863
CellaVision AB hereby declares, under our sole responsibility, that the device described above complies with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 and commission delegated directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.

This Declaration of Conformity is based on RoHS Declarations of Conformity received from CellaVision AB's suppliers and comprises all applicable components, spare parts, and accessories, associated with the device described above

Applied Common Specifications and Standards

EN ISO 13485:2016	Quality Management System - Requirements for regulatory purposes
EN ISO 14971:2019	Application of risk management to medical devices

Lund, 2024-02-29



Charlotte Oom, Director Quality, Clinical and Regulatory Affairs
Person Responsible for Regulatory Compliance

Product name	Article No.	Basic UDI-DI	GMDN
Device/Analyzer			
CellaVision DC-1	XU-10301	735004097XU-10301AH	61864
CellaVision DC-1 PPA	XU-10302	735004097XU-10302AK	61864
Accessories			
CellaVision DM Software 7.1.X DC-1	CDMS-017199	07350040977156	43472
CellaVision® Remote Review Software - Professional Edition, version independent, hardware license key	CRRS-PR0099	735004097CRRSB5	43472
CellaVision® Remote Review Software - Team Edition, version independent	CRRS-TE0099	735004097CRRSB5	43472
CellaVision® Remote Review Software - Group Edition, version independent	CRRS-GR0099	735004097CRRSB5	43472
CellaVision® Remote Review Software - Enterprise Edition, version independent	CRRS-EN0099	735004097CRRSB5	43472
CellaVision® Remote Review Software, Enterprise Edition upgrade from Group Edition, Non expiring license	CRRS-ENGR99	735004097CRRSB5	43472
CellaVision® Remote Review Software, Enterprise Edition upgrade from Team Edition, Non expiring license	CRRS-ENTE99	735004097CRRSB5	43472
CellaVision® Remote Review Software, Group Edition upgrade from Team Edition, Non expiring license	CRRS-GRTE99	735004097CRRSB5	43472