

## EU DECLARATION OF CONFORMITY

<b>Manufacturer</b>	CellaVision AB Mobilvägen 12 SE-223 62 LUND SWEDEN
<b>Single registration no.</b>	SE-MF-000002377
<b>Products</b>	CellaVision® DM9600 including accessories, medical device software and associated software products pertinent to the device, see table below
<b>IVDR classification</b>	A
<b>IVDR Conformity assessment procedure</b>	Annex XI of (EU) 2017/746 of the European Parliament

### Intended use of the CellaVision® DM9600

The CellaVision® DM9600 is an automated cell-locating device.

The CellaVision® DM9600 automatically locates and presents images of blood cells on peripheral blood smears. The operator identifies and verifies the suggested classification of each cell according to type.

The CellaVision® DM9600 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

### Intended use of the CellaVision Peripheral Blood Application

The CellaVision Peripheral Blood Application is intended for differential count of white blood cells, characterization of red blood cell morphology and platelet estimation.

The system automatically locates and presents images of blood cells on peripheral blood smears. The operator identifies and verifies the suggested classification of each cell according to type.

**Intended use of the CellaVision Advanced RBC Application** The CellaVision® DM9600 with the CellaVision Advanced RBC Application is an automated cellocating device intended for in-vitro diagnostic use.

The CellaVision® DM9600 with the CellaVision Advanced RBC Application automatically locates and presents images of blood cells on peripheral blood smears. The operator identifies and verifies the suggested classification of each cell according to type.

The CellaVision® DM9600 with the CellaVision Advanced RBC Application is intended for analyzing blood samples that an automated cell counter has flagged as abnormal.

CellaVision® DM9600 with the CellaVision Advanced RBC Application is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

### Intended use of the CellaVision Body Fluid Application

CellaVision® DM9600 is an automated system intended for in-vitro diagnostic use.

The Body Fluid Application is intended for differential count of white blood cells. The system automatically locates and presents images of cells on cytocentrifuged body fluid preparations. The operator identifies and verifies the suggested classification of each cell according to type.

DM9600 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

**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
<b>Device/Analyzer</b>			
CellaVision® DM9600	XU-10288-01	735004097XU-10288BJ	61864
<b>Accessories</b>			
CellaVision® DM Software 7.1.X DM9600	CDMS-977199	07350040977170	43472
CellaVision® DM Software for DM9600, upgrade from version 5.0.x or higher to version 6.0.x Includes upgrade for CellaVision® DM9600, CellaVision® Remote Review Software and CellaVision® Server Software.	CDMS-976050	735004097CDMS8G	43472
CellaVision® DM Software for DM9600, upgrade from version 6.0 or higher to version 6.0.x Includes upgrade for CellaVision® DM9600, CellaVision® Remote Review Software and CellaVision® Server Software.	CDMS-9760UP	735004097CDMS8G	43472
CellaVision® DM Software for DM9600, upgrade from version 5.0.x or higher to version 7.0.x Includes upgrade for CellaVision® DM9600, CellaVision® Remote Review Software and CellaVision® Server Software.	CDMS-977050	735004097CDMS8G	43472
CellaVision® DM Software for DM9600, upgrade from version 6.0 or higher to version 7.0.x Includes upgrade for CellaVision® DM9600, CellaVision® Remote Review Software and CellaVision® Server Software.	CDMS-977060	735004097CDMS8G	43472
CellaVision® Remote Review Software, License renewal, 1 year, Independent of version	CRRS-000001	735004097CRRSB5	43472
CellaVision® Remote Review Software, Conversion of Annual license to Non expiring license, Independent of version	CRRS-000099	735004097CRRSB5	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
CellaVision® Remote Review Software, Enterprise Edition, upgrade from Citrix Ready, Enterprise Edition	CRRS-ENXXUP	735004097CDMS8G	43472
CellaVision® Remote Review Software, Team Edition, upgrade from Citrix Ready, Team Edition	CRRS-TEXXUP	735004097CDMS8G	43472
CellaVision® Oil Pack, 2x150 mL	XU-10135-01	735004097XU-10135AQ	61864

Product name	Article No.	Basic UDI-DI	GMDN
Magazine Pack, Peripheral Blood, Orange, 10 pcs	XU-10133-01	735004097XU-10133AL	61864
Magazine Pack, Body Fluids, Blue, 5pcs	XU-10134-01	735004097XU-10134AN	61864
<b>Medical Device Software – Applications (Optional)</b>			
CellaVision® Advanced RBC Application Non-expiring license for CellaVision® DM9600. Requires CellaVision® DM Software version 5.0 or higher.	CAR-970099	735004097CAREZ	43472
CellaVision® Body Fluid Application Non-expiring license for CellaVision® DM9600. Requires CellaVision® DM Software version 5.0 or higher. Includes one Magazine Pack, Body Fluids, Blue, 5 pcs.	CBF-970099	735004097CBFEC	43472
Package containing: CellaVision® Advanced RBC Application Non-expiring license for CellaVision® DM9600. CellaVision® Body Fluid Application Non-expiring license for CellaVision® DM9600. Requires CellaVision® DM Software version 5.0 or higher. Includes one Magazine Pack, Body Fluids, Blue, 5 pcs.	CAB-970099	735004097CABDZ	43472