EU DECLARATION OF CONFORMITY

Manufacturer	CellaVision AB Mobilvägen 12 SE-223 62 LUND SWEDEN
Single registration no.	SE-MF-000002377
Products	Automated Digital Cell Morphology Analyzer DI-60 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 Automated Digital Cell Morphology Analyzer DI-60
The Automated Digital Cell Morphology Analyzer DI-60 is an automated cell-locating device.

The Automated Digital Cell Morphology Analyzer DI-60 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 Automated Digital Cell Morphology Analyzer DI-60 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 DI Advanced RBC Application
The Automated Digital Cell Morphology Analyzer DI-60 with the Advanced RBC Application is an automated cell-locating device intended for in-vitro diagnostic use.

The Automated Digital Cell Morphology Analyzer DI-60 with the 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 Automated Digital Cell Morphology Analyzer DI-60 with the Advanced RBC Application is intended for analyzing blood samples that an automated cell counter has flagged as abnormal. The Automated Digital Cell Morphology AnalyzerDI-60 with the 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 DI Body Fluid Application
Automated Digital Cell Morphology Analyzer DI-60 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.

Automated Digital Cell Morphology Analyzer DI-60 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
Device/Analyzer			
Automated Digital Cell Morphology Analyzer DI-60	CC286297	735004097CC286297T7	61864
Accessories			
CellaVision® DM Software Ver. 7.X for DI-60	CQ092642	07350040976234	43472
DI Remote Review Software, version independent, Hardware license key.	AG516335	735004097CRRSB5	43472
CellaVision® DM Software, upgrade from version 4.0 or higher to version 7.x.x. Includes upgrade for Digital Microscope Equipment DI-60, DI Remote Review Software and CellaVision® Server Software.	CE297676	735004097CDMS8G	43472
CellaVision® DM Software, upgrade from version 6.0.1 or higher to version 7.x.x. Includes upgrade for Digital Microscope Equipment DI-60, DI Remote Review Software and CellaVision® Server Software.	AX312698	735004097CDMS8G	43472
CellaVision® DM Software, upgrade from version 4.0 or higher to version 6.x.x. Includes upgrade for Digital Microscope Equipment DI-60, DI Remote Review Software and CellaVision® Server Software.	AW736222	735004097CDMS8G	43472
CellaVision® DM Software, upgrade from version 6.0.1 or higher to version 6.x.x. Includes upgrade for Digital Microscope Equipment DI-60, DI Remote Review Software and CellaVision® Server Software.	BS914899	735004097CDMS8G	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, Enterprise Edition, upgrade from Citrix Ready, Enterprise Edition	CRRS-ENXXUP	735004097CDMS8G	43472
CellaVision® Remote Review Software, Group Edition upgrade from Team Edition, Non expiring license	CRRS-GRTE99	735004097CRRSB5	43472
CellaVision® Oil Pack, 2x150 mL	XU-10135-01	735004097XU-10135AQ	61864

Product name	Article No.	Basic UDI-DI	GMDN
CellaVision® Remote Review Software, Team Edition, upgrade from Citrix Ready, Team Edition	CRRS-TEXXUP	735004097CDMS8G	43472

Product name	Article No.	Basic UDI-DI	GMDN
Medical Device Software – Applications (Optional)			
DI Advanced RBC Application Non-expiring license for Digital Microscope Equipment DI-60. Requires CellaVision® DM Software version 5.0 or higher.	AB859211	735004097CAREZ	43472
DI Body Fluid Application Non-expiring license for Digital Microscope Equipment DI-60. Requires CellaVision® DM Software version 4.0.1 or higher.	AG241722	735004097CBFEC	43472
Package containing: DI Advanced RBC Application Non-expiring license for Digital Microscope Equipment DI-60. DI Body Fluid Application Non-expiring license for Digital Microscope Equipment DI-60. Requires CellaVision® DM Software version 5.0 or higher.	CK257542	735004097CABDZ	43472