
EC DECLARATION OF CONFORMITY

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|---|---|
| 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 | See Instructions for Use |

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

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

Lund, 2022-07-04



Johan Attelid, QA/RA Specialist
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® 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 |