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Effective Date: 2025-09-09

Version:

Author:

Approver:

Reviewer:

EU Declaration of Conformity

Manufacturer information

Legal Manufacturer



CathVision
Lygten 37
2400 Copenhagen NV
Denmark

Single Registration Number (SRN)

DK-MF-000008517

Product Information

Basic UDI-DI

(8013)57000021685ECGENIUSR2LP

Product Name

ECGenius™ System

REF

CVT-0069 R3.2

Risk Class

IIB, rules 9 and 11

Intended Use/ Intended Purpose

The ECGenius™ System is a measurement system intended to acquire, filter, digitize, amplify, display, record electrocardiac signals obtained during electrophysiological procedures. The ECGenius™ System can acquire, filter, digitize, amplify, display, record signals from connected external 3rd party devices such as stimulator, ablation generator, blood pressure transducers, and cardiac mapping systems. The ECGenius™ System can make available acquired ECG and IECG analog signals with external third-party devices and display analog signal from an external third-party device.

The ECGenius™ System allows electrophysiologists to view signals real time and review recorded signals. Interpretation of signals, possible diagnosis and therapeutic approach is performed by and under the responsibility of the electrophysiologist. The ECGenius™ System is intended to be used in hospital and clinics and is indicated for adult patients (age 18 or older) who are eligible for electrophysiological procedures.

Conformity Assessment Procedure

ANNEX IX Quality Management System and assessment of technical documentation, section 4

Common Specifications

None Applicable

Notified Body (NB)

KIWA Assurance B.V.
Vijzelmolenlaan 7
3447 GX Woerden
The Netherlands

NB Identification Number

1912

(EC) Certificate

20M00035CRT02

This Declaration of Conformity is issued under the sole responsibility of CathVision. We declare that the products covered by this declaration are in conformity with the following applicable union legislation.

- (EU)2017/745 Regulation on Medical Devices
- 2012/19/EU Directive on waste electrical and electronic equipment (WEEE)
- 2015/863/EC and 2011/65/EC Directive on restriction of use of certain hazardous substances

Signed for and on behalf of

CathVision ApS

Electronic Signature, see the following page

Name: Søren Skovsen
Position: Director of QA/RA
Date: 2025-09-09, Copenhagen, Denmark

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Revision History	
Major version	Overall description of change
1	Declaration of Conformity for CVT-0069 R2.0 ECGenius™ System
2	Catalogue number (REF) has been updated from R2.0 to R3.2 in conjunction with update of hardware and software components in the ECGenius™ System Kiwa Dare B.V. has changed name to KIWA Assurance B.V.

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Signatures:

Controlled Document Approved:	I hereby state that I have found no errors in the contents of this controlled quality document. The document is ready for release.
Name:	Søren Friis Skovsen cathvision.com\sfs
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