



## EC DECLARATION OF CONFORMITY

We,

RVC Medical IT B.V.  
De Brand 10-19  
3823 LH AMERSFOORT, The Netherlands

hereby declare under our sole responsibility that the CE marked products to which this declaration relates,

### **RVC Clinical Insight**

*Standalone software intended for viewing medical images and other medical data resulting from functional and diagnostic exams with the purpose of letting physicians perform diagnosis or do treatment planning.  
RVC Clinical Insight offers measurement functionality and image processing (ECG signal filtering)*

have been classified as **Class IIa** according to Annex IX, by virtue of Rule 10,

and are in conformity with the essential requirements and provisions of the **Council Directive 93/42/EEC** (2007/47/EG) concerning medical devices,

and are subject to the procedure set out in Annex II of the Council Directive 93/42/EEC.

The conformity of the designated product with the provisions of the applied Directive(s) is proved by full compliance with the following standards (harmonised):

<i>Reference number</i>	<i>Title</i>	<i>Date of Issue</i>
EN ISO 13485	Medical devices – Quality Management Systems – Requirements for Regulatory Purposes	2016
EN ISO 14971	Medical devices – Application of risk management to medical devices	2012
EN 1041	Information supplied by the manufacturer of medical devices	2008+A1:2013
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2016



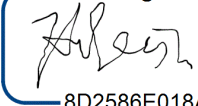
<i>Reference number</i>	<i>Title</i>	<i>Date of Issue</i>
EN IEC 62304	Medical device software - Software life-cycle processes	2006/A1:2015
EN IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	2015/C11:2016

This declaration of conformity is made on base of the quality assurance  
ISO 13485 certificate N°. **BE15/223575796**  
delivered by Notified Body N° 1639, SGS Belgium nv, valid from: 10 JUN 2021  
and

CE certificate N°. **BE 16/819942424**  
delivered by Notified Body N° 1639, SGS Belgium nv, valid from: 02 MAR 2021

Signature :

Date : 30-jun-21 | 05:51 CEST

DocuSigned by:  
  
8D2586E018A4497...

Name : Joost van Geijn  
Function : CEO