



## 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 Assistant**

*Software for acquiring, archiving, visualisation, quantification, reporting and analysis of digital medical images, values and signals which are the result of functional and diagnostic exams.*

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):

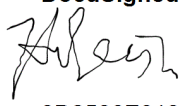
<i>Reference number</i>	<i>Title</i>	<i>Date of Issue</i>
EN ISO 13485	Medical devices – Quality Management Systems – Requirements for Regulatory Purposes	2016
EN ISO 14971	Medical devices – Application of risk management to medical devices	2012
EN 1041	Information supplied by the manufacturer of medical 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
EN IEC 62304	Medical device software - Software life-cycle processes	2006/AC:2008
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 :

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

Name : J.A. van Geijn  
Function : CEO