EC Certificate Full Quality Assurance System: Certificate BE16/819942424

The management system of

RVC Medical IT B.V.

De Brand 10 - 19
3823 LH Amersfoort, The Netherlands

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

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.

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.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 02 March 2021 until 09 June 2023
and remains valid subject to satisfactory surveillance audits.
Issue 5. Certified since 30 September 2016

Certification is based on reports numbered BE/AMD 14/1229.QMD

Authorised by

Global Medical Devices Certification Manager

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