Number: 2245058CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Thirona BV

Toernooiveld 300
6525 EC Nijmegen
The Netherlands
SRN ID.: N/A

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2192634CN

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Principal Certification Manager

First Issued: **16 September 2020** Date: **15 July 2021** Expiry date**: 1 September 2025**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra-product-safety.com Company registration 09085396

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This certificate covers the following device(s) / groups of device(s):

Software (MDA0315, class IIa)
Lung Q v1.x.y RetCAD v2.x.y

VARIOUS DIAGNOSTIC AND INTEROPERATIVE BIOIMAGING INSTRUMENTS – SOFTWARE (Z11039082, Class IIb)	
CAD4TB v. 7.x.y	*Intended Purpose:* CAD4TB is a software product that takes a single frontal chest radiograph from a subject of at least 4 years old as input, in the form of a DICOM image, and produces several outputs. These outputs include a quality assessment of the input image, a heat map indicating possible abnormal areas, and a score that is monotonically related to the likelihood that the radiograph is radiologically abnormal. Users can take these outputs into account in their clinical work: they can decide if a new image should be acquired, in case the quality assessment indicates suboptimal image quality; they can decide that the subject should undergo further testing for the presence of tuberculosis (TB) or other lung diseases, in case the heat map displays suspicious regions that are verified by a human operator as suspicious, or when the score is above a certain threshold. The choice for this threshold should be made by the user and will depend on the conditions under which the software is used.

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Conditions for or limitations to the validity of this certificate:

- N/A

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Date of Issue certificate	Certification Notice Reference	Action
16 September 2020	2192634CN13	First issue
15 July 2021	2192634CN14	Revised

First Issued: **16 September 2020** Date: **15 July 2021** Expiry date**: 1 September 2025**

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