

Number: 2245855CE01

EU Quality Management System Certificate

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

Manufacturer:

Aidence B.V.

Sarphatikade 8
1017 WV Amsterdam
The Netherlands

SRN ID.: NL-MF-000000534

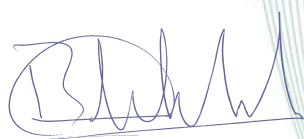
DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2198606CN

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: **28 October 2020**

Date: **26 March 2021**

Expiry date: **1 October 2025**

© Integral publication of this certificate and adjoining reports is allowed

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

Number: 2245855CE01

EU Quality Management System Certificate

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

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

Various digital bioimaging management instruments – software (Z110690, class IIb)

Basic UDI-DI: ++B865VeyeLungNodules4H

Veye Lung Nodules V3.x.y

Intended Purpose: Assist physicians in their review of CT scans in the detection, classification, quantification and growth assessment of solid and sub-solid pulmonary nodules using low-dose or standard-dose and non-contrast or post-contrast scans with a maximum axial slice thickness of ≤3mm. Veye lung Nodules is intended for use as a second or concurrent reader.

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 |
|---------------------------|--------------------------------|-------------|
| 28-10-2020 | 2198606CN06 | First issue |
| 9-12-2020 | 2198606CN07 | Revised |
| 26-03-2021 | 2198606CN08 | Revised |

First Issued: **28 October 2020**

Date: **26 March 2021**

Expiry date: **1 October 2025**

© Integral publication of this certificate and adjoining reports is allowed

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