

CERTIFICATE

Number: 2251156

The management system of:

Aidence B.V.

Sarphatikade 8
1017 WV Amsterdam
The Netherlands

Manufacturer Facility Identifier F006108

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 4 -
Production Quality Assurance Procedure

Canada: Medical Devices Regulations - Part 1- SOR 98/282

United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:

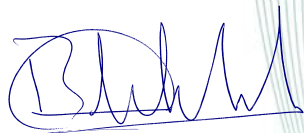
Design and development, manufacture, installation and servicing of computer aided diagnosis in the area of radiology.

Certificate expiry date: 2025-04-01

Certificate effective date: 2022-08-17

Certified since: 2022-08-17

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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The validation of the validity of this certificate can be checked through DEKRA's website using the following link:

<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

