ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 127113 0001 Rev. 00

Holder of Certificate: **Nexus Intelligence (Pty) Ltd**
125 Dallas Avenue
9th Floor Menlyn Central Office Tower
Pretoria
0181 SOUTH AFRICA

Facility(ies): **Nexus Intelligence (Pty) Ltd**
125 Dallas Avenue, 9th Floor Menlyn Central Office Tower,
Pretoria, 0181 SOUTH AFRICA

See Scope of Certificate

Certification Mark:

Scope of Certificate: **Design and Development, Production, Service, and Installation of Standalone Medical Device Software Application for the analysis of Medical Images and /or Medical Data with Notification System.**

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 127113 0001 Rev. 00

Report No.: TPS5217
Valid from: 2025-12-18
Valid until: 2028-12-17

Date, 2025-12-18

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 127113 0002 Rev. 00

Manufacturer:

Nexus Intelligence (Pty) Ltd
125 Dallas Avenue
9th Floor Menlyn Central Office Tower
Pretoria
0181 SOUTH AFRICA

SRN Manufacturer - ZA-MF-00044903

Authorized Representative:

TNMC Devices Limited Liability Company
Krezmina 1, 10000 Zagreb, CROATIA

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III (excluding custom-made implantable devices) or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G15 127113 0002 Rev. 00

Report No.: TPS5217
Valid from: 2025-12-18
Valid until: 2030-12-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-12-18

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Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 127113 0002 Rev. 00

Classification:	Class IIb
Device Group:	Z110305 - RADIOLOGY INSTRUMENTS
Intended Purpose:	Nexus AI CXR 1.0 is a computer-aided detection (CADe) software application intended for use in the analysis of anterior-posterior (AP) and posterior-anterior (PA) chest X-rays (CXR) to support clinical decision-making. The software identifies: • Normal chest X-rays and, • Radiological abnormalities suggestive of pulmonary tuberculosis (TB).
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2025-12-18	TPS5217	Initial issuance

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