## EC CERTIFICATE

## **Full Quality Assurance System**

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-880-200-2004

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC. certifies that the manufacturer:

Mediso Ltd. Labore utca 3. 1037 Budapest Hungary

for the products / product category:

Single and multi-modality imaging devices and software for the area of nuclear medicine / radiology

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: NE/1030/2020

This certificate is valid until 2024-05-26 supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by NEOEMKI LLC as a Notified Body with identification number 1011.

This certificate is valid only with the attachment.

Issue: 2

First issued by the Directorate of Device Testing and Clinical Engineering (EMKI) on 17 April 2020.

Budapest, 2020-07-27





EMKI 2511

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft. neoEMKI National Medical Device Conformity Assessment and Certification LLC.











## ATTACHMENT TO EC CERTIFICATE

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## Additional information for Certificate No. 5-880-200-2004

The certificate is valid for the following products / models:

Single and multi-modality imaging devices and software for the area of nuclear medicine / radiology

	Class
AnyScan / AnyScan DUO SPECT/CT/PET	IIb
AnyScan S / AnyScan DUO SPECT	IIa
AnyScan SC / AnyScan DUO SPECT/CT	IIb
AnyScan DUO CT Upgrade	IIb
AnyScan PC / AnyScan PET/CT	IIb
AnyScan TRIO SPECT	IIa
AnyScan TRIO SPECT/CT	IIb
AnyScan TRIO CT Upgrade	IIb
AnyScan TRIO SPECT/CT/PET	IIb
InterView FUSION	IIa
InterView XP	IIa
Nucline TH-22 (Gamma Camera)	IIa
Nucline TH-33 (Gamma Camera)	IIa
Nucline TH-45 (Gamma Camera)	IIa

Issue: 2

László Imre Managing Director





First issued: 2020-04-17

**EMKI** 

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft. neoEMKI National Medical Device Conformity Assessment and Certification LLC.



Date: 2020-07-27