

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.
Laborc 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


László Imre
Managing Director



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.

H-1097 Budapest, Albert Flórián út 3/A, tel: +36 20 268 75 95, e-mail: cert@emki.hu
www.emki.hu



ATTACHMENT TO EC CERTIFICATE

Page 1 of 1

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

The certificate is valid for the following products / models:

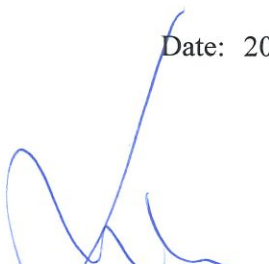
*Single and multi-modality imaging devices and software
for the area of nuclear medicine / radiology*

	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

Date: 2020-07-27

First issued: 2020-04-17


László Imre
Managing Director



EMKI

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

H-1097 Budapest, Albert Flórián út 3/A, tel: +36 20 268 75 95, e-mail: cert@emki.hu
www.emki.hu

