EC Declaration of Conformity

We herewith declare that the medical device

Product:	**AnyScan S / AnyScan DUO SPECT**
Short description of the product:	Dual head SPECT System
GMDN Code(s):	40642 Nuclear medicine system, SPECT, rotating detector head
Serial number:	**AS-xxxxxx-S**
Product classification:	Class II.a – according to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD)

under sole responsibility of the manufacturer

Manufacturer:	Mediso Ltd.
Address:	Laborc utca 3., H-1037 Budapest, Hungary
Phone:	+36-1-3993030
Fax:	+36-1-3993040
E-mail:	info@mediso.hu

meet(s) the provision of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD).

This declaration is approved by the Quality System Certificate with

NB Certificate Registration No.:	5-794-200-1608
Validity:	2022-08-22

issued by:

Notified Body:	National Institute of Pharmacy and Nutrition, Directorate of Device Testing and Clinical Engineering (EMKI)
Notified Body Identification No.:	1011

The medical device specified above meets the essential requirements set out in Annex I of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD), which apply to it, taking account of the intended purpose of the device.

Manufacturer specified above follows the below-specified procedure (i.e. Conformity Assessment Route) set out in Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD) relating to EC declaration of conformity of the medical device specified above in order to affix CE marking on the medical device.

Conformity Assessment Route: Annex II. excluding (4) Full quality assurance system

Digitally signed by Matei Vasile
Date: 2022.01.25 11:25:06 EET
Reason: MoldSign Signature
Location: Moldova

CE 1011

Mediso
Medical Imaging Systems

The medial device complies with the harmonized standards listed below:

ID of the harmonized standard	Title of the harmonized standard
MSZ EN 1041:2008+A1:2014	Information supplied by the manufacturer of medical devices
MSZ EN ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes (ISO 13485:2016)
MSZ EN ISO 14971:2013	Medical devices. Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
MSZ EN ISO 15223-1:2017	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements (ISO 15223-1:2016; Corrected version 2017-03)
MSZ EN 60601-1:2017	Medical electrical equipment. Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
MSZ EN 60601-1-2:2016	Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests (IEC 60601-1-2:2014)
MSZ EN 60601-1-6:2010+A1:2015	Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability (IEC 60601-1-6:2010+A1:2013)
MSZ EN 62304:2006+A1:2016	Medical device software. Software life-cycle processes (IEC 62304:2006+A1:2015)
MSZ EN 62366-1:2015	Medical devices. Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015)

All supporting documentation is retained at the premises of the manufacturer.

Place and Date of Issue: Budapest, 2020-02-04

The undersigned, representing the manufacturer:

István BAGAMÉRY
Managing Director

CE 1011