145003-20-09-28

EC CERTIFICATE

Full Quality Assurance System

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

CE Certiso Ltd. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

Limited Liability Company Research and Production Enterprise "DX-SYSTEMS"

Headquarters: **Ukraine, 61072, Kharkiv, Tobolska st. 42, office 501**

Authorised representative: **Nilas MV GmbH**
Jacobsenweg 13, 22525 Hamburg, Germany

Scope:

Active programmable diagnostic medical devices

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Electroence-phalographic computer complexes	DX BRAINTEST PLUS	Computer electroence-phalograph system for EEG and EP recording and analysis with digital video monitoring feature	DX BRAINTEST PLUS BioFeedback	II.a
			DX BRAINTEST PLUS Basic	
			DX BRAINTEST PLUS Standard	
			DX BRAINTEST PLUS Extended	
			DX BRAINTEST PLUS Polygraph	

This certificate is valid only in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 161-CE-170904

Issue: 1
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Start date of certified status: 28 September 2020

CE Certiso
Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Valter PAPP, Dr.
General Manager

Expires:
01 April 2024

CE Certiso Ltd.
NB2409
Notified Body

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