144758-18-06-18

EC CERTIFICATE

Full Quality Assurance System

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

CE Certiso Kft. (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:

Uscom Research, Development and Manufacturing Ltd.

Headquarters: **1119 Budapest, Boglárka utca 17., Hungary**

Scope:

Respiratory measurement and diagnostic devices, including spirometers and software

The certificate covers the following devices:

Description of the device	Type	Intended use	Risk class
PC Spirometer	SpiroTube PC	pulmonary function diagnostics and monitoring	IIa
	Pneumos PC*		
Mobile Handheld Spirometer	OTTHON		
	Pneumos 500*		
Bluetooth Spirometer	SpiroTube Mobile Edition		
	Pneumos BT		

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

ID number of the related audit report: **117-CE-171122**

Issue: 4
Issued: 21 May 2021
First issued: 18 June 2018
Start date of certified status: 08 April 2015, *18 June 2018

Expires:
17 June 2023

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

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NB ID number: 2409