144758-18-06-18

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:

Thor Laboratories Kft.

Headquarters: **8000 Székesfehérvár, Raktár utca 2., Hungary**

Manufacturing plant: **1119 Budapest, Pajkos utca 50., 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
Mobile Edition BlueTooth Spirometer	SpiroTube ME		IIa
Mobile Handheld Spirometer	SpiroThor		IIa
Mobile Handheld Spirometer	OTTHON		IIa

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

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

Issue: 1
Issued: 18 June 2018
First issued: 18 June 2018
Start date of certified status: 08 April 2015

Expires:
17 June 2023

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