Digitally signed by Lungu Ion
Date: 2023.06.28 12:58:56 EEST
Reason: MoldSign Signature
Location: Moldova

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate number: 145179-21-12-14

Name of certified organisation:

UTAS Technologies s.r.o

Headquarters:

1 Stavitelska str., Bratislava 83104, Slovakia

Scope:

Design, production, sales and service of active medical devices used in the intensive care

CE Certiso Kft. certifies that the quality management system applied by the organisation above meets the requirements of the following standard on the listed scope:

MSZ EN ISO 13485:2016
(ISO 13485:2016)

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

Issue: 2
Issued: 04 January 2022
First issued: 14 December 2021
Start date of certified status: 14 December 2018

Valter PAPP, dr.
General Manager

Expires:
13 December 2024

ISO 13485

NAH-4-0136/2019
MANAGEMENT SYSTEM CERTIFICATION BODY

CE Certiso Kft.
H-2092 Budakeszi, Erdő utca 101.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu

144941-19-06-18

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:

UTAS Technologies s.r.o

Headquarters: **Stavitel'ska 1, 831 04 Bratislava, Slovakia**

Scope:

Lung Ventilators UVENT-S

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Lung Ventilators	UVENT-S	respiratory station for high-class respiratory support and continuous comprehensive patient monitoring	UVENT-A-S UVENT-T-S UVENT-M-S	IIb

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

ID number of the related audit report: 176-CE-180605

Issue: 1
Issued: 18 June 2019
First issued: 18 June 2019
Start date of certified status: 18 June 2019

Valter PAPP, Dr.
General Manager

Expires:
03 April 2024

CE Certiso Ltd.
NB2409
Notified Body

CE Certiso Ltd.
H-2040 Budaörs, Gyár u. 2.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409

UTAS Technologies s.r.o.

1, Stavitelska St.
83104 Bratislava
Slovakia

REG: 48 146 480
VAT: SK2120093382
Tel.: +421 220 620 001

DECLARATION OF CONFORMITY

to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Manufacturer: **UTAS Technologies s.r.o.,**
Stavitel'ska, 1, Bratislava, Slovakia, 831 04

Product: **LUNG VENTILATORS UVENT-S**
models UVENT-A-S, UVENT-T-S, UVENT-M-S

Classification: Class II b, according to the Rule 10, Annex IX of the MDD

Conformity assessment route: Annex II, Clause 3

We, the Manufacturer, herewith declare that the stated medical devices to be in compliance with requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 2007/47/EC of the European Parliament and of the council of 5 September 2007. All supporting documentation is retained at the premises of the manufacturer
This Declaration applies to the lung ventilators with serial numbers starting from № V.300.17001.0001

Standards applied:

EN 60601-1:2015;
EN 60601-1-6:2010;
EN 60601-2-49:2015;
EN 794-3:1998;
EN 62366:2008;
EN ISO 14971:2012;
EN 60601-1-2:2015;
EN 60601-1-8:2007;
EN 80601-2-12:2012;
EN 1041:2008;
ISO 15223-1:2016
EN ISO 13485:2016.

Notified Body: **CERTISO**
H-2092 Budakeszi, Erdo utca 101., HUNGARY

Identification number: CE 2409

EC Certificate: **144941-19-06-18**

Date of issue: **18.06.2019**

Expiry date: **03.04.2024**

Signature:

Volodymyr Hervasii
Director

UTAS TECHNOLOGIES S.R.O. UTAS IČO: 48146480

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