

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 Company Ltd

Headquarters: **2a, Marii Kapnist str., Kyiv, Ukraine, 03057**

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

Scope:

Patient monitors UM 300 with or without central station UNET

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Patient monitors	UM 300	continuous monitoring of patient's vital signs	UM 300-10 UM 300-15 UM 300-20	IIb
Patient monitors UM 300 with central station UNET	UNET	The software system that provides the reception, analysis, documentation in real time of information about the status of patients coming from patient monitors UM 300.	UM 300-10 UM 300-15 UM 300-20 with central station UNET	IIb

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

ID number of the related audit report: **192-CE-191010**

Issue: 2

Issued: 4 February 2021

First issued: 14 April 2020

Start date of certified status: 14 April 2020

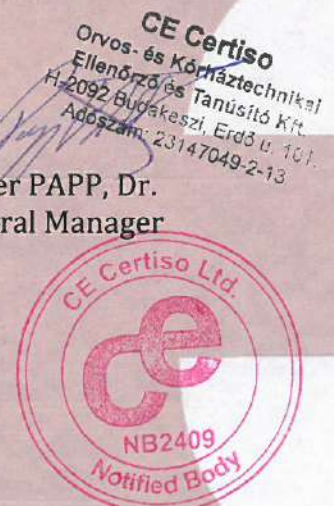
Expires:

25 May 2024

CE Certiso Ltd.
H-2092 Budakeszi, Erdő utca 101.
Tel.: +36 23 880 830 / info@cecetiso.hu / www.cecetiso.hu
NB ID number: 2409



Valter PAPP, Dr.
General Manager



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Staviteľ'ska, 1, Bratislava, Slovakia, 831 04

Scope:

Lung Ventilators UVENT

The certificate covers the following devices:

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

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

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



Certificate number: 144993-20-04-14

Name of certified organisation:

UTAS Company Ltd

Headquarters:

2a, Marii Kapnist str., Kyiv, Ukraine, 03057

Scope:

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

CE Certiso Ltd. 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)**

Issue: 1


Issued: 14 April 2020

First issued: 14 April 2020

Start date of certified status: 14 April 2020

Expires:

13 April 2023


Valter PAPP, dr.
General Manager

CE Certiso
Orvos-és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
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