

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:

Patient monitors UM 300-S
with or without central station UNET-S

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Patient monitor	UM 300-S	continuous monitoring of patient's vital signs	UM 300-10-S UM 300-15-S UM 300-20-S	IIb
Patient monitors UM 300-S with central station UNET-S	UNET-S	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-S.	-	II.b

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

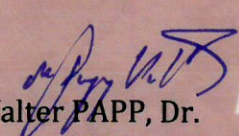
ID number of the related audit report: 176-CE-180605

Issue: 2

Issued: 24 September 2019

First issued: 04 April 2019

Start date of certified status: 04 April 2019


Valter PAPP, Dr.
General Manager

Expires:

03 April 2024



Certificate number: 145179-21-12-14

Name of certified organisation:

UTAS Technologies s.r.o

Headquarters:

1 Staviteľská 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:

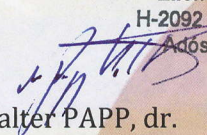
**MSZ EN ISO 13485:2016
(ISO 13485:2016)**

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

Expires:
13 December 2024

CE Certiso

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


Valter PAPP, dr.
General Manager

