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144878-19-04-04

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:

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

Expires:
03 April 2024

Valter PAPP, Dr.
General Manager

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

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

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

Manufacturer: **UTAS Technologies s.r.o.,**
1 Stavitelska str., Bratislava 831 04, Slovakia

Product: **UM 300-S PATIENT MONITORS**
models UM 300-10-S, UM 300-15-S, UM 300-20-S
with central station UNET-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 the following standards:

Standards applied: EN ISO 14971:2012; EN ISO 13485:2016

Electric safety:
EN 60601-1:2015;
EN 60601-1-6:2010; EN 60601-1-8:2007
EN 60601-2-27:2014; EN 80601-2-30:2013;
EN 60601-2-34:2014; EN 60601-2-49:2015;

Electromagnetic compatibility:
EN 60601-1-2:2015; IEC 61000-3-2:2014;
IEC 61000-3-3:2013+AMD1:2017; IEC 61000-4-2:2008;
IEC 61000-4-3:2006 +AMD1:2007+AMD2:2010;
IEC 61000-4-4:2012; IEC 61000-4-5:2014 +AMD1:2017;
IEC 61000-4-6:2013; IEC 61000-4-8:2009;
IEC 61000-4-11:2004/A1:2017.

Exposure of electromagnetic radiance standards: Not applied

Notified Body: **CE Certiso Orvos- es Korhaztechnikai Ellenorzo es Tanusito Kft. (NB 2409)**
Erdő utca 101, 2092 Budakeszi, Hungary

Identification number: CE 2409

EC Certificate: **144878-19-04-04**

ISO Certificate: **145179-21-12-14**

Date of issue: **28.01.2022**

Expiry date: **28.01.2024**

Signature:

Volodymyr Hervasii
Director

UTAS TECHNOLOGIES S.R.O. IČO: 48146480

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