

## DECLARATION OF CONFORMITY

**Manufacturer:** **UTAS Technologies s.r.o.,**  
1 Staviteľska 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 or without 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 **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.

Our Quality Management System meets the requirements of **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices

This Declaration applies to the Patient Monitors with serial numbers starting from № M.652.06015.0018

**Standards applied:**

EN 60601-1:2015;	EN 60601-1-2:2017;	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;	EN 1041:2008;
IEC 62304:2006;	ISO 10993-1:2018;	EN 62366:2008;
ISO 15223-1:2016;	EN ISO 14971:2019;	EN ISO 13485:2016.

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

**NB identification number:** 

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

**ISO Certificate:** **145233-24-12-14**

**Date of issue:** **14.12.2024**

**Expiry date:** **31.10.2025**

**DoC Ref. number:** TF-UM/UNET/F-19/D-01/v 9.0

**Signature:**  Maksym Dichek, Director

## DECLARATION OF CONFORMITY

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

**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

Our Quality Management System meets the requirements of **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices

This Declaration applies to the lung ventilators with serial numbers starting from № V.300.17001.0001

**Standards applied:**

EN 60601-1:2015;	EN 60601-1-2:2017;
EN 60601-1-6:2010;	EN 60601-1-8:2007;
EN 60601-2-49:2015;	EN 80601-2-12:2012;
EN 794-3:1998;	EN 1041:2008;
IEC 62304:2006;	ISO 10993-1:2018;
EN 62366:2008;	ISO 15223-1:2016
EN ISO 14971:2019;	EN ISO 13485:2016.

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

**NB identification number:** 

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

**ISO Certificate:** 145233-24-12-14

**Date of issue:** 14.12.2024

**Expiry date:** 31.10.2025

**DoC Ref. number:** TF.UVENT/F-19/D-01/v 12.0

**Signature:**  Maksym Dichek, Director

**Certificate number: 145233-24-12-14**

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)**

Issue: 1  
Issued: 14 December 2024  
First issued: 14 December 2024  
Start date of certified status: 14 December 2018

Expires:  
**13 December 2027**

**CE Certiso**

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

  
Valter PAPP, dr.  
General Manager

