EC CERTIFICATE
Full Quality Assurance System

Certificate no.:
10000312812-PA-NA-CZE Rev.3.0

Initial certification date:
08 September 2020

Valid Until:
27 May 2024

This is to certify that the management system of

Triton Electronic Systems Ltd
Sibirskiy Trakt str. 12/5, 620100, Ekaterinburg, Russian Federation

For design, production, and final product inspection/testing of:

Respiratory Gas Monitoring Devices

has been assessed and found to comply with respect to:

the conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

Place and date:
Høvik, 20 May 2021

For the issuing office:
DNV Product Assurance AS
Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Sholeh Gheissar
Principal Assessor

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

Jurisdiction
Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate History		
Revision	**Description**	**Issued Date**
0.0	Original Certificate	08 September 2020
1.0	Extension in scope - new product AMG 06 added	04 January 2021
2.0	Administrative corrections	05 February 2021
3.0	Extension in scope – new trademark "QuRe" added in the **List of Models dated 21.04.2021**	20 May 2021

Products covered by this Certificate:		
Product Description	**Product Name**	**Class**
Mainstream CO2 sensor with accessories	Mainstream CO2 sensor TESM.506001 Airway adapter adult/pediatric TESM.706020 Airway adapter pediatric/neonatal TESM.706021 Model names and trademarks are described in **the List of Models dated 21.04.2021**	IIb
Multigas Analyzer	Multigas Analyzer AMG-06 TESM.943129.002	IIa

Sites covered by this certificate	
Site Name	**Site Address**
Triton Electronic Systems Ltd	Sibirskiy Trakt str. 12/5, 620100, Ekaterinburg, Russian Federation

EU Representative
Wladimir Wollert, Otto-Selzerstraße 16, D-97340, Marktbreit, Germany

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.