EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10000312812-PA-NA-CZE rev.2.0	PRJC-600254-2019-PRC-CZE	27 May 2024

This is to certify that the quality 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 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

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 05 February 2021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Alessandra Rinna

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

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	Issue 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

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	IIb
Multigas Analyzer	Multigas Analyzer AMG-06 TESM.943129.002	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	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

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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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 of Presafe.

End of Certificate