

Declaration of Conformity

Manufacturer: *Triton Electronic Systems Ltd.*
Sibirskiy Trakt str. 12/5, 620100, Ekaterinburg, Russia

EU-Representative: *Wladimir Wollert,*
Otto-Selzer Straße 16, D-97340 Marktbreit, Germany

Medical device: *Intensive Care Ventilator Zisline: MV200, MV300* (including parts and accessories of the device, see Annex)

We herewith declare on our own responsibility that the above mentioned medical device meets all the applicable requirements according to Annex II – excluding Section 4 of the Directive 93/42/EEC. This document covers all possible configurations of the medical device (see Annex).

This declaration is valid till 15.01.2022.

Notified body: *mdc medical device certification GmbH*,
Kriegerstraße 6, 70191 Stuttgart, Germany

Notified Body ID: 0483

Quality Director

V.M. Polunin

2020

Ekaterinburg, Russia



Triton Electronic Systems Ltd.

Legal address:
Shevchenko str., 9, 217
Ekaterinburg, Russia, 620027

Factory address:
Sibirskiy Trakt str., 12/5
Ekaterinburg, Russia, 620100

phone: +7 (343) 304-60-57
e-mail: info@treat-on.com
www.treat-on.com

EN ISO 13485
CE 0483

Annex to the Declaration of Conformity

Name		Part number	Manufacturer	Configuration					
				MV200			MV300		
				K0	K1	K2	K0	K1	K2
1.	Intensive Care Ventilator Zisline	TESM.941144.001-01	Triton Electronic Systems Ltd, Russian Federation	+					
		TESM.941144.001-01-01			+				
		TESM.941144.001-01-02				+			
		TESM.941144.001-01-03					+		
		TESM.941144.001-01-04						+	
		TESM.941144.001-01-05						+	
	including:								
1.1.	electronic unit	TESM.230001	Triton Electronic Systems Ltd, Russian Federation	+					
		TESM.230001-01			+				
		TESM.230001-02				+			
		TESM.230002					+		
		TESM.230002-01						+	
		TESM.230002-02						+	
1.2.	filter-regulator	TESM.186143	Triton Electronic Systems Ltd, Russian Federation	+	+	+	+	+	+
1.3.	high pressure oxygen hose	TESM.046002-01	Triton Electronic Systems Ltd, Russian Federation	*	*	*	*	*	*
1.4.	mainstream CO ₂ sensor	TESM.506001	Triton Electronic Systems Ltd, Russian Federation	O	+	+	O	+	+
1.5.	pulse oximetry sensor, reusable, clip, adult	RM.501.00.124-01	Triton Electronic Systems Ltd, Russian Federation	O	O	O	O	O	O
1.6.	pulse oximetry sensor, reusable, wrap, neonatal	RM.501.00.004-01	Triton Electronic Systems Ltd., Russian Federation	O	O	O	O	O	O
Note:									
1) The device configuration is defined by the variant (MV200 or MV300) and the delivery set.									
2) "+" – available in the device configuration.									
3) "O" – option in the device configuration.									
4) "*" – available in the device configuration, but this part number (type) is defined when ordering.									

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