

Document No.: VMT-CE-001**CE TECHNICAL FILE (VORTRAN Automatic Resuscitator, VAR)**

Item	Doc. No.	Title	Rev. No.	Issuing Date	Remark
1.0	VMT-CE-001-01	Declaration of Conformity	A	05-30-2012	

1.1 Manufacturer

Name: VORTRAN Medical Technology 1, Inc.
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1.2 European Representative

Name: Katalytic Ltd.
Address: Old School House, Merchant Taylors Close, Ashwell, Herts SG7 5LF UK
Contact: Katrina McCarthy
E-mail: Katrina@katalytic.co.uk
Telephone: 011-44-1462 743-989

Product Name: VORTRAN Automatic Resuscitator (VAR)

Model Numbers: VAR-PCM and VAR-PTM (Attached Figure / Brochure).

Classification: MDD IIb

Classification and Relevant Rule of MDD: MDD Annex IX, Rule 11;

Rational: VAR is a valve that opens and closes to allow continuous flow of air/oxygen to be delivered in and out of the patient body.

UMDNS code: 13360

GMDN code: 57981

CE Conformity Assessment Route: Annex II.3 of MDD

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the premises of the manufacturer and the European Representative. Manufacturer is exclusively responsible for the declaration of the conformity. Manufacturer declares that this is the only application filed for this product and with no other notified body.

1.3 Directives

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 JUNE 1993 concerning medical devices (93/42/EEC), ANNEX II.

Notified Body: TUV SUD Product Service, GmbH Ridlerstrabe, 6580339 MUNCHEN, Germany

Identification Number: **0123**

CE Certificate No.: _____

Expiry date of CE Certificate: _____

Date of start of CE Marking: _____

Signature of issuing person: _____

Name: Reza Saied

Position: Vice President Engineering / Regulatory

Date: _____

Place: Manufacturer site as stated above.