

CEN DOCUMENT RISK MANAGEMENT REPORT REVISION NUMBER 01/2011

CLASS I

Declaration of Conformity

April 30, 2013

Manufacturer: Traverse Rescue, LLC

Manufacturer's Address: 2460 Tedlo Street

Mississauga, Ontario

L5A 3V3

Class Of Device: Class 1

Identification: 2 Piece Yellow Floatation Collar

Intended Use: Patient Transport/ Rescue Equipment

Model No.: 11-0124A

In accordance with the European Community Council Directive 93/42/EEC; Annex VII, Traverse Rescue, LLC declares the products that bear the CE mark conform with all the provisions of this Directive that apply to them.

The 2 pc Floatation Collars have been determined to be class I devices according to article 9.1 and using classification criteria from Annex IX of the Directive.

Traverse Rescue, LLC or its representative will make available upon request all applicable technical documentation to allow assessment of conformity of its products in accordance with Annex VII; section 2 and 3.

Traverse Rescue, LLC has a systematic procedure in place to review experience gained from its devices in the post-production phase, taken appropriate corrective action based on this experience and report malfunctions to the competent authorities in accordance with Annex VII; section 4.

Sophia Hatsisavvas General Manager