



*Supplying the world with safety.*

## Product CE Marking

To **The Conformity Department**  
**The Medicines and Healthcare Products Regulatory Agency**

This document is a Declaration of Conformity of Q'Straint products with the relevant sections of the Essential Requirements of European Council Directive 93/42/EEC Medical Devices as a Class I Medical Device.

This declaration regarding Q'Straint products is made with full acknowledgment of the requirements for non sterile products given in Annex VII of the Directive 93/42/EC

Compliance with the requirements of Annex VII of the Directive may be verified by inspection of the relevant product Technical File on request.

## General description of purpose and function of the products.

The Q'Straint range of wheelchair tie-downs and occupant restraint systems are intended to secure a wide range of forward facing manual and powered wheelchairs and restrain a wheelchair occupant when a wheelchair is used as a seat in a road passenger vehicle.

Products in the Q'Straint range are designed for use in vehicle categories M1, M2 and M3 as defined in the EU Consolidated Resolution on the Construction of Vehicles.

The design and performance requirements for Q'Straint wheelchair tie-down and occupant restraint systems intended for use in specified vehicle categories are taken from known UK Statutory Regulation, European Directive, UNECE Regulation and ISO Standards.

The Q'Straint range of products are allocated kit numbers which, for the purposes of this declaration, will be referred to specify the intended vehicle category for application.

Q'Straint wheelchair tie-down and occupant restraint system kits for use in road passenger vehicles will undergo the full process of Risk Analysis, Risk Evaluation, Risk Control and Post Production Surveillance following the principles given in BS EN ISO 14971:2007 Application of Risk Management to Medical Devices.

Signed

A handwritten signature in black ink, appearing to read 'Andy Taylor', with the initials 'AT' written above it.

Print Name                      Andy Taylor

Position                         Plant Manager

Date                                June 2008



Unit 72-76, John Wilson Business Park  
Whitstable, Kent CT5 3QT, United Kingdom  
Tel: (01227) 773035 Fax: (01227) 770035  
E-mail: info@qstraint.co.uk  
Web Site: www.qstraint.com

