

# E.C. DECLARATION OF CONFORMITY

(REVISED 230414)

COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

## REHABILITATION MANUFACTURING SERVICES LTD

Thompson House, Unit 10, Styles Close, Sittingbourne, Kent ME10 3BF

### DECLARES that ...

**Pelvic Positioning Belts and Harness** devices manufactured by RMS Ltd., specifically for Invacare UK Ltd and as described within the RMS Ltd., Technical Data File TDF17:-

- Conform to Class 1 requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
- Are in conformity with the provisions of that Directive and, where such is the case, with the national standards transposing harmonised standards as noted within the Technical Data File 17.
- The requirements of Annex I, Annex VII, Annex IX have been followed for Class I devices and registration requirements of Article 14 have been notified to the UK Competent Authority. In support of these requirements the company follows a quality management system based on BS EN ISO 9001:2008.
- All Pelvic Positioning Belts and Harnesses, manufactured by RMS Ltd., are intended for use with a medical device, (a Wheelchair or Special Seating System). As such, they are classed as accessories to a medical device. They are classified as Class 1, by virtue of Rule 1 and that no other rules apply. (Annex IX of Council Directive 93/42/EEC concerning medical devices).

This Declaration covers all Pelvic Belts and Harnesses manufactured by RMS Ltd., specifically for supply to Invacare (UK) Ltd. and subsequently placed on the market by Invacare (UK) Ltd., on or after 1<sup>st</sup> January 2010.

This declaration applies until such time as a renewed declaration of conformity is raised.

#### DEVICE OR MODEL NAME(S)

**Pelvic Positioning Belts** Invacare Part Numbers: 1525289, 1525290, 1525291, 1525292, 1525293, 1525294, 1525295, 1525296 and 1525297.

RMS allocated numbers: BMB-001S BMB-002S

**Harnesses (various)** Invacare Part Numbers: 1525269, 1525270, 1525271, 1525272, 1525273, 1525274, 1525275, 1525276, 1525277, 1525278, 1525279, 1525280, 1525281, 1525282, 1525283, 1525284 and 1525285.

This declaration is signed on behalf of Rehabilitation Manufacturing Services Limited by :

SIGNED .....

NAME .....W. COTTER.....

POSITION .....DIRECTOR.....

DATE .....23 APRIL 2014.....

**RMS**  
REHABILITATION MANUFACTURING SERVICES

Technical Data File No.17 Pelvic Positioning Belts and Harnesses (INVACARE)