MANUFACTURER'S DECLARATION OF CONFORMITY

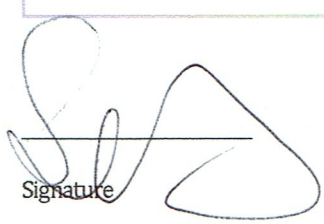
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

DECLARATION OF CONFORMITY PROCEDURES

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	Sleep Specialists, LLC
Business address:	150 Monument Rd, Suite 207, Bala Cynwyd PA 19004 USA
Medical device(s):	Zzoma Positional Sleeper
Classification:	Class I
GMDN code and term:	Pillow, specify [40512] A device designed for supporting or positioning some part of the body. The pillow consists of a casing stuffed with a variety of possible materials feathers, flock or foam rubber. It may also be filled with fluids. The case may also be made of a variety of materials. The pillow may also have additional outer protective coverings drawn over it.
Scope of application:	All Zzoma Positional Sleepers

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.	
Standards applied:	• Medical Device Directive 93/42/EEC • ISO 13485:2003 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes (Note: Sleep Specialists, LLC is not ISO 13485:2003 certified, but their contract manufacturer is ISO 13485:2003 certified.) • EN 980:2008 Graphical Symbols for Use in Labeling of Medical Devices • EN 1041:2008 Information Supplied by the Manufacturer with Medical Devices • ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Device



Signature

Sila Yesilsoy

Executive Vice President

Jan 23 2015

Date