

EC Declaration of Conformity

Déclaration CE de Conformité

This is to certify that the
Cette déclaration signifie que le

(Overlay)mattress and accessories
(SUR)MATELAS et ses accessoires

AXTAIR AUTOMAX

Manufactured by:

Fabriqué par :

ASKLESANTE groupe WINNCARE

200 rue Charles Tellier
Zone Industrielle de Grézan
30 000 Nîmes – France

Conforms to the requirements of Council Directive 93/42/EEC relating to
Medical Devices Class 1 Product

Est conforme aux dispositions de la Directive Européenne 93/42/EEC applicables
aux dispositifs médicaux de classe 1

Registration: FR/CA01/0809093V

By application of the following standards

Par application des normes suivantes:

EN ISO 14971 v2007 – Medical devices – Application of risk management to medical devices

EN 12182 – Technical aids for disabled persons – General requirements and tests methods

NF EN ISO 13485 v 2004 – Medical devices – Quality management system

For and on behalf of : ASKLESANTE groupe WINNCARE

<p>Executive Manager Christophe CASTELLANO</p>
<p>p/o P ESPINASSE, Affaires Réglementaires et Médicales</p> 