

EC Declaration of Conformity

Déclaration CE de Conformité

This is to certify that the
Cette déclaration signifie que le

AXTAIR AXENSOR® CUSHION

Coussin Axtair Axensor®

Manufactured by:
Fabriqué par :

ASKLESANTE groupe WINNCARE
ACTIPARC - ZI de Grézan – 200 rue Charles Tellier
30 034 Nîmes Cedex 1 – France

Conforms to the requirements of Council Directive 93/42/EEC – 2007/47/EEC relating to
Medical Devices Class 1 Product

Conforms to the requirements of Council Directive 1995/5/EC relating to Radio and
Telecommunication Terminal Equipment

Est conforme aux dispositions de la Directive Européenne 93/42/CEE – 2007 / 47 CEE applicables
aux dispositifs médicaux de classe 1

Est conforme aux dispositions de la Directive Européenne 1995/5/CE applicables aux terminaux de
télécommunication et aux équipements radio

Registration: ANSM number

By application of the following standards

Par application des normes suivantes:

EN ISO 14971 v2013 – Medical devices – Application of risk management to medical devices

EN 12182 v 2012 – Technical aids for disabled persons – General requirements and tests methods

NF EN ISO 13485 v 2003 – Medical devices – Quality management system

NF EN ISO 60601-1 Medical electrical equipment – Part 1 : General requirements for basic safety and essential performance

EN 301 489-17 - EN 300 328 - Electromagnetic compatibility and Radio spectrum Matters (ERM).

For and on behalf of : ASKLESANTE groupe WINNCARE

Executive Manager Jean Pierre SAULNIER
Date: <i>13/05/2014</i>
Signature: 

