



SYSTEMAM®

DECLARATION CE DE CONFORMITE CONFORMEMENT A L'ANNEXE VII DE LA DIRECTIVE 93/42/CEE
*DECLARATION OF CONFORMITY IN COMPLIANCE WITH ANNEX VII OF THE EUROPEAN MEDICAL DEVICES
DIRECTIVE 93/42/ECC*

Je soussigné, Sébastien Cinquin, PDG de la société SYSTEM ASSISTANCE MEDICAL SAS,
assure et déclare que le dispositif de classe I (règle I de l'annexe IX) :
*I, Sébastien Cinquin, President of System Assistance Medical SAS, assure and declare that the below
mentioned device of class I (index I of annex IX) :*

PI01M-PI02M :
Matelas d'aide à la prévention des escarres
Mattress for bedsore preventing

satisfait aux dispositions du décret qui lui est applicable.
Conforms to requirements of the applicable decree.

Cette déclaration s'appuie sur la documentation technique I528DV.
This declaration is based on technical documentation I528DV.

De ce fait, ce dispositif est conforme aux exigences essentielles selon l'annexe I de la
directive.
*Therefore, this device is in conformity with the essential requirements according to the Annex I of
directive.*

Le Lédats, le 3 Octobre 2014
Sébastien Cinquin,





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ANNEXE A LA DECLARATION CE DE CONFORMITE DU DISPOSITIF DE CLASSE I
ANNEXE TO THE DECLARATION OF CONFORMITY FOR THE CLASS I DEVICE

PI01M-PI02M :

Matelas d'aide à la prévention des escarres
Mattress for bedsore preventing

Item n° : PI01MPLPFAL - PI01MPLPFALBX - PI01MPLPFALNC - PI01MPLPFALNCBX -
PI01MPLPFDH - PI01MPLPFDHBX - PI01MPLPFDHNC - PI01MPLPFDHNCBX -
PI01MPLPMHI - PI02MFLPMHI - PI02MFLPMHINC - PI02MPLMHII10 - PI02MPLPMHF -
PI02MPLPMHF190 - PI02MPLPMHF190NC - PI02MPLPMHF80 - PI02MPLPMHF80NC -
PI02MPLPMHFNC - PI02MPLPMHI - PI02MPLPMHI - PI02MPLPMHII00 -
PI02MPLPMHII00NC - PI02MPLPMHII10 - PI02MPLPMHII10NC - PI02MPLPMHII20 -
PI02MPLPMHII20NC - PI02MPLPMHII40 - PI02MPLPMHII40NC - PI02MPLPMHII90 -
PI02MPLPMHI220 - PI02MPLPMHI80 - PI02MPLPMHI80BX - PI02MPLPMHI80NC -
PI02MPLPMHIBX - PI02MPLPMHINC - PI02MPLPMHINCBX

Le Lédats, le 3 Octobre 2014
Sébastien Cinquin,

