

ATTESTATION CE / EC CERTIFICATE

Approbation du Système d'assurance Qualité de la Production (limitée à la fonction de mesurage)

Approval of Production Quality Assurance System (related to a measurement function)

ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant / Manufacturer

PELSTAR LLC

9500 West 55th St.

McCook, IL 60525 UNITED STATES

Catégorie du(des) dispositif(s) / Device(s) category

Pèse-personnes pour patients pouvant inclure une toise

Patient weighing scales that could include height measuring rod

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T000322-1-R, T000322-4-DOCR, le système d'assurance qualité - pour la conformité des produits aux exigences métrologiques - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.

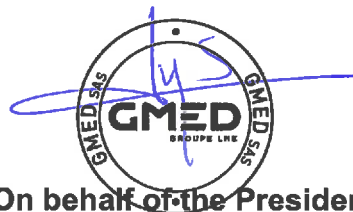
GMED certifies that, on the basis of the results contained in the file referenced T000322-1-R, T000322-4-DOCR, the quality system - related to the conformity of the products with metrological requirements - of medical devices listed here aboved complies with the requirements of the Directive 93/42/EEC, annex V section 3.

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : October 26th, 2018 (included)

Valable jusqu'au / Expiry date : July 1st, 2021 (included)



**On behalf of the President
Béatrice LYS
Technical Director**

Identification des dispositifs / Identification of devices

Description du Dispositif Médical <i>Medical Device Description</i>	Référence Commerciale du Dispositif Médical <i>Medical Device Commercial Reference Number</i>	Classe du Dispositif Médical <i>Medical Device Class</i>
Weight measurement only		
Digital Physician Scales	752xx-yy	I (measure)
Digital Pediatric Scales	525xx-yy	I (measure)
Digital Platform Scales	2400xx-yyyy, 2500xx-yyyy, 2600xx-yyyy, 2650xx-yyyy, 2700xx-yyyy	I (measure)
Professional Home Healthcare Scales	160xx	I (measure)
Weight and height measurement		
Digital Physician Scales	499xx-yy, 501xx-yy, 597xx-yy, 599xx-yy, 600xx-yy	I (measure)
Digital Pediatric Scales	523xx-yy	I (measure)
Digital Platform Scales	1100xx-yyyy, 2101xx-yyyy, 3001xx-yyyy	I (measure)
Mechanical Physician Column Scales	402xx, 450xx	I (measure)

Where "xx" is defined as lb, kg, or kl (weight units pre-set at factory), and "yy" is Bluetooth option, and "yyyy" is handrail or Bluetooth option.

Ce certificat couvre le site et activités suivants :
This certificate covers the following site and activities:

Pelstar, LLC
 9500 West 55th Street
 Mc Cook, IL 60525
 USA

Fabrication, contrôle final / Manufacturing, final control



GMED	0459
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On behalf of the President
Béatrice LYS
 Technical Director