EC Certificate Full Quality Assurance System: Certificate / certificat
FR96/8324

The management system of

COUSIN BIOTECH s.a.s.

8, Rue de l'Abbé Bonpain,
F59117 WERVICQ-SUD, France

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Directive 93/42/EEC

on medical devices, Annexe II (section 4 exclue)

The scope of registration appears on page 2 and 3 of this certificate.
Le domaine de certification apparaît en page 2 et 3 de ce certificat.

This certificate is valid from 7 March 2011 until 1 May 2015
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2 May 2013
Issue 26. Certified since 31October 1996

Le certificat est valable du 07 mars 2011au 01 mai 2015
et reste valide jusqu'à décision satisfaisante à l'issue des audits de suivi.
Date de renouvellement de certification 02 mai2013
Version 26. Certifié depuis 31 octobre 1996

Certification is based on reports numbered FR/MD 06953
This is a multi-site certification.
Additional site details are listed on subsequent pages.
Ceci est une certification multisite
La liste des sites additionnels est mentionnée dans les pages suivantes

Authorised by

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SGS CE 01 1210 M3 FR

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Issue / Version 26

For the following products

Non-resorbable parietal reinforcement implants (Abdominal plug and meshes and reinforcement plug and meshes abdominal wall); Adjustable gastric banding; Non resorbable articular ligaments; Non resorbable elastic ligaments; Anchor devices; Devices for the interspinous space (with spinous support or with laminar support); Intervertebral prostheses; Cervical discal prostheses; Urogenital implants (Suburethral support tape and Implant for the treatment of prolapse); Non-resorbable Trapezium Implants; Trial Prostheses. Suture devices for mesenchymateous tissues - Cruralink®.

Adhesix® Parietal Reinforcement Meshes with one adhesive side; Resorbable (PLLA) trapezium implants; Biocage® & Bioscorp® Vertebral Fusion Cages; Semi-Resorbable Meshes, Plugs and Films: Biomesh® SR, 4DDOME®, Biomesh® CA.B.S.'Air ® SR, Semi Resorbable Reinforcement Parietal Implant; Biomesh® COH and Biomesh® COL wall reinforcement meshes coated with porcine collagen; Resorbaid® Resorbable Poly L-Lactic Acid (PLLA) Ligaments (and System for Reinforcing Achilles Tendons); Neurological Patches: Biomesh ™ N1, N2, N3, N3L and N4, Cranial and Spinal Dura Mater Substitutes; Adjustable gastric banding with adhesive mesh support for the implantable port - Adhesix® - Bioring®.

Non-implantable medical devices for visceral, gynaecological and urological surgery comprising: Sterile ancillary device for surgical mesh.

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

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on medical devices, Annexe II (section 4 exclue)
Issue / Version 26

For the following products

Implants de renforcement pariétal non résorbables (plaques et plugs abdominaux et plaques et plugs de renforcement de la paroi abdominale); Anneaux gastriques ajustables ; Ligaments articulaires non résorbables ; Ligaments élastiques non résorbables; Dispositifs d'ancrage; Dispositifs pour l'espace inter-épineux (avec appui épineux ou avec appui lamaire); Prothèses intervertébrales ; Prothèses de disque cervical ; Implants urogénitaux (Bandelettes de support sous-urétrales et Implants pour le traitement du prolapsus); Implants Trapéziens non-résorbables ; Prothèses d'essai. Dispositifs de suture des tissus mésenchymateux - Cruralink®.

Adhesix® Implants de renforcement pariétal adhésifs ; Implants Trapéziens résorbables (PLLA) ; Cages de fusion vertébrale: Biocage® & Bioscorp® ; Plaques, Plugs et Films semi résorbables : Biomesh® SR, 4DDOME® and Biomesh® CA.B.S.'Air SR®, Implant de renforcement pariétal semi-résorbable; Biomesh® COH et Biomesh® COL : plaques de renforcement de paroi imprégnées de collagène porcin ; Resorbald®: Ligaments résorbables en acide Poly L-Lactique (PLLA) (et Systèmes de renforcement de tendons d'Achille) ; Patchs neurologiques Biomesh® N1, N2, N3, N3L et N4, Substituts de la dure mère crânienne et spinale ; Anneau gastrique ajustable avec système de fixation adhésif de la chambre implantable Adhesix® - Bioring®.

Dispositifs médicaux non-implantables pour la chirurgie viscérale, gynécologique et urologique, comprenant : Dispositif ancillaire stérile pour pose de plaques chirurgicales.

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

Additional facilities / Sites additionnels

Allée des Roses, F-59117 WERVICQ-SUD, France