Certificate / Certificat FR16/81842421

The management system of / Le système de management de

SOCIETE DE GESTION MEDICALEX s.a.s

20, Avenue Aristide Briand, 92220 Bagneux, France

has been assessed and certified as meeting the requirements of
a été audité et certifié selon les exigences de

ISO 13485:2003
EN ISO 13485:2012

For the following activities / Pour les activités suivantes

Purchasing and Distribution of medical devices.

Achat et distribution de dispositifs médicaux.

This certificate is valid from 28 November 2016 until 31 March 2019
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 March 2019
Issue 1. Certified since 29 May 1998

Le certificat est valable du 28 novembre 2016 au 31 mars 2019
et reste valide jusqu'à décision satisfaisante à l'issue des audits de suivi.
L'audit de renouvellement doit avoir lieu avant 31 mars 2019
Version 1. Certifié depuis 29 mai 1998

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485-2 0614 FR

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Certificate / Certificat FR98/13880

The management system of / Le système de management de

FRANCEMED S.A.R.L

20, Avenue Aristide Briand, 92220 Bagneux, France

has been assessed and certified as meeting the requirements of
a été audité et certifié selon les exigences de

ISO 13485:2003
EN ISO 13485:2012

For the following activities / Pour les activités suivantes

Design, manufacturing, packaging and sales of sterile and non-sterile implants, surgical and non-surgical instruments and custom made devices. Subcontracting packaging of medical devices.

Conception, fabrication, conditionnement et vente d'implants steriles et non-stériles, d'instrumentation associée à usage chirurgical ou non chirurgical, et de dispositifs sur mesure. Conditionnement à façon de dispositifs médicaux.

This certificate is valid from 28 November 2016 until 31 March 2019
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 March 2019
Issue 22. Certified since 29 May 1998
Le certificat est valable du 28 novembre 2016 au 31 mars 2019
et reste valide jusqu'à décision satisfaisante à l'issue des audits de suivi.
L'audit de renouvellement doit avoir lieu avant 31 mars 2019
Version 22. Certifié depuis 29 mai 1998

Authorised by

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UKAS MANAGEMENT SYSTEMS
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Certificate FR14/018472

The management system of

FRANCEMED S.A.R.L

20, Avenue Aristide Briand, 92220 Bagneux, France

has been assessed and certified as meeting the requirements of

ISO 13485:2003

For the following activities

The scope of registration appears on page 2 of this certificate.

Effective Date 28 November 2016 Expiry Date 31 December 2018
Re certification audit due before 31 December 2018
Valid subject to satisfactory surveillance audits.
Issue 4. Certified since 16 January 2014

Authorised by
Jan Saunders – Business Manager

SCC Accredited CB-MS
OCSM Accrédité CCN ™

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CMDCAS recognised registrar

SGS 13485 CMDCAS 0311 M2

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FRANCEMED S.A.R.L

ISO 13485:2003

Issue 4

Detailed scope

Design and manufacturing of :

Sterile and non-sterile Osteosynthesis implants (wires, nails, cerclage wire, pin tip, staples, plates, screw plates, nail-plates, screws, buttons, washers, blade-plates).

Sterile and non-sterile Thoracic implants (staples, thoracic plates).

Sterile Hip prosthesis implants (stop screws, acetabular supports, greater trochanter hooks, stainless steel modular femoral heads).

Sterile and non-sterile Spinal implants (rods, spinal plates, spondylolisthesis plates and screws, external fixation systems).

Sterile and non-sterile Pediatric implants (telescopic nails, derotation plates, screw-plates, blade plates, fork blade-plates, osteotomy plates, nail-plates, slipped capital femoral epiphysis fixations).

Sterile Hand implants (Ungueal prosthesis).

Sterile and non sterile Foot implants (Hallux valgus sets, Interposition cupulas).

Sterile bowl and spatula for cement preparation.

Non-sterile trial prosthesis (hip, knee and thoracix prosthesis).

Non-sterile Instruments with measuring function (stem measuring tool, gauge, sight of angle and protractor, femoral head measuring tool, bone forceps, pressure indicator).

Non-sterile ancillary devices and drills for surgery.

SCC Accredited CB-MS OCSM Accrédité CCN TM

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EC Certificate Full Quality Assurance System: Certificate/Certificat FR98/13881

The management system of / Le système de management de

FRANCEMED S.A.R.L

20, Avenue Aristide Briand, 92220 Bagneux, France

has been assessed and certified as meeting the requirements of
a été audité et certifié selon les exigences de

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Directive 93/42/EEC

Dispositifs médicaux, Annexe II (section 4 exclue)

For the following products / Pour les produits suivants

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

This certificate is valid from 28 November 2016 until 29 May 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 29 May 2019
Issue 25. Certified since 29 May 1998

Le certificat est valable du 28 novembre 2016 au 29 mai 2021
et reste valide jusqu'à décision satisfaisante à l'issue des audits de suivi.
L'audit de renouvellement doit avoir lieu avant 29 mai 2019
Version 25. Certifié depuis 29 mai 1998

Certification is based on reports numbered FR/MD 08803
Cette certification est basée sur les rapports numérotés FR/MD 08803

Authorised by/Autorisé par

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
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SGS CE 02 0315 M4 FR

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FRANCEMED S.A.R.L

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Directive 93/42/EEC

Dispositifs médicaux, Annexe II (section 4 exclue)

Issue / Version 25

Detailed scope/Domaine d'activité détaillé

Osteosynthesis implants, Sterile and non sterile, including:
Wires, Nails, Cerclage wires, Pin tips, Staples, Plates
Screw-plates, Nail-plates, Screws, Washers
Buttons, Blade-plates

Thoracic implants, Sterile and non sterile, including:
Staples (Borrelly's staples)
Thoracic Plates

Hip prosthesis, Sterile and non sterile, implants including:
Anti-luxation stop-screws
Acetabular supports
Greater trochanter hooks
Modular stainless steel femoral head

Spinal implants, Sterile and non sterile, including:
Luque's rods
Spinal plates
Spondylolisthesis plates
Spondylolisthesis screws
External fixation implants (Cranial Halo & Gardner Tractor)

Pediatric implants, Sterile and non sterile, including:
Telescopic nails, Derotation plates, Screw-plates
Blade-plates, Fork blade-plates
Osteotomy plates, Nail-plates
Slipped capital femoral epiphysis fixations

Hand implants, Sterile, including:
Ungueal prosthesis

Foot implants, Sterile and non sterile, including:
Hallux valgus sets
Interposition cupulas

Sterile and non-sterile PEBORD instruments for Percutaneous Bone Resection Drilling including drill bits, trephines and reamers.
Non sterile drills, reamers, taps, augers, snap on screwdriver.
Non-sterile trial prosthesis for hip, knee and thorax.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

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FRANCEMED S.A.R.L

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Directive 93/42/EEC

Dispositifs médicaux, Annexe II (section 4 exclue)

Issue / Version 25

Detailed scope/Domaine d'activité détaillé

Implants d'ostéosynthèse, stériles et non-stériles comprenant:
Broches, Clous, Fils de cerclage, Embout de broches
Agrafes, Plaque , Vis-plaques, Clous-plaques
Vis, Rondelles, Boutons, Lames-plaques

Implants thoraciques, stériles et non-stériles, comprenant:
Agrafes de Borrelly
Plaques thoraciques

Prothèse de hanche, stériles et non-stériles, comprenant:
Butées anti-luxation
Fonds de cotyle
Crochets pour grand trochanter
Têtes modulaires inox

Implants du rachis, stériles et non-stériles, comprenant:
Tiges de Luque
Plaques rachidiennes
Plaques pour spondylolisthèsis
Vis pour spondylolisthèsis
Fixateurs externes (Halo Crânien et Etrier de Gardner)

Implants pédiatriques, stériles et non-stériles, comprenant:
Clous télescopiques, Plaques de dérotation, Vis-plaques,
Lame-plaques , Pique-plaques, Plaques d'ostéotomie,
Clous-plaques, Vis à épiphysiolyse

Implants pour la main, stériles, comprenant:
Implants unguéal

Implants pour le pied, stériles et non-stériles, comprenant:
Hallux valgus set
Cupule d'interposition

Instruments FROP stériles et non-stériles pour la résection osseuse par fraisage percutané incluant: mèches, trépans et alésoirs.
Forêts, alésoirs, tarauds, tarières, tournevis encliquetable, non-stériles.
Prothèses d'essai non-stériles pour la hanche, le genou et le thorax.

Lorsque le périmètre ci-dessus inclus un Dispositif Médical de classe III, un certificat d'examen CE de Conception (ECDE) suivant l'annexe II (section 4) valide, en addition du présent certificat est une exigence obligatoire pour la mise sur le marché de chaque dispositif

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EC Certificate Production Quality Assurance System: FR13/018028

The management system of

FRANCEMED S.A.R.L

20, Avenue Aristide Briand, 92220 Bagneux, France

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

Directive 93/42/EEC

on medical devices, Annexe V
Limité aux aspects de fabrication concernés par la conformité des produits selon les exigences métrologiques.

For the following products

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

This certificate is valid from 28 November 2016 until 29 May 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 29 May 2019
Issue 24. Certified since 29 May 1998
Le certificat est valable du 28 novembre 2016 au 29 mai 2021
et reste valide jusqu'à décision satisfaisante à l'issue des audits de suivi.
L'audit de renouvellement doit avoir lieu avant 29 mai 2019
Version 24. Certifié depuis 29 mai 1998

Certification is based on reports numbered FR/MD 08803

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
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FRANCEMED S.A.R.L

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

Directive 93/42/EEC

on medical devices, Annexe V
Limité aux aspects de fabrication concernés par la conformité des produits selon les exigences métrologiques.

Issue / Version 24

Detailed scope

Non sterile devices with measuring function, including:
Stem measuring tool
Gauge
Sight of angle and protractor
Femoral head measuring tool
Weil's measuring tool
Dynamic compression system for pectus carinatum deformities treatment.

Dispositifs non-stériles avec fonction de mesurage, comprenant:
Mesureur de tige
Jauge
Viseur d'angle et rapporteur
Mesureur de tête fémorale
Pince de Weil
Système de compression dynamique destiné au traitement des malformations de type pectus carinatum.

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