ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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Location: Moldova

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 05 32283 045

Manufacturer:

Biomatlante SA
ZA les Quatre Nations
5, Rue Edouard Belin
44360 Vigneux de Bretagne
FRANCE

Product Category(ies):

Calcium phosphate bone substitutes; (non-active implants)
Resorbable fixation systems (Polylactic and composite screws; composite sheaths);
Collagen implants from porcin origin (Membranes)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713077573_2

Valid from: 2018-01-15
Valid until: 2022-11-26

Date, 2018-01-15

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 05 32283 045

Facility(ies):

Biomatlante SA ZA les Quatre Nations
5, Rue Edouard Belin, 44360 Vigneux de Bretagne, FRANCE

Biomatlante SA Pôle Bio-Ouest
Rue du Moulin de la Rousselière, 44800 Saint Herblain, FRANCE

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 032283 0057 Rev. 00

Manufacturer:

Biomatlante SA
ZA les Quatre Nations
5, Rue Edouard Belin
44360 Vigneux de Bretagne
FRANCE

Product:

Fixation systems

Resorbable Fixation Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: **713128484**

Valid from: **2019-03-14**
Valid until: **2022-12-06**

Date, **2019-03-14**

Stefan Preiß

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 032283 0057 Rev. 00

Facility(ies): **Biomatlante SA**
ZA les Quatre Nations, 5, Rue Edouard Belin, 44360 Vigneux de Bretagne, FRANCE

Model(s): **Composite Interference Screw**
Polylactic Interference Screw

Parameter:

Numéros d'articles Articles Numbers	Model(s) names	Type/Paramètres Type/Parameters	Material
08CPVI0725	Composite Interference Screw	**D 7x L 25**	Calcium Phosphate - Polymer
08CPVI0730	Composite Interference Screw	**D 7 x L 30**	Calcium Phosphate - Polymer
08CPVI0825	Composite Interference Screw	**D 8 x L 25**	Calcium Phosphate - Polymer
08CPVI0830	Composite Interference Screw	**D 8 x L 30**	Calcium Phosphate - Polymer
08CPVI0925	Composite Interference Screw	**D 9 x L 25**	Calcium Phosphate - Polymer
08CPVI0930	Composite Interference Screw	**D 9 x L 30**	Calcium Phosphate - Polymer
08CPVI1030	Composite Interference Screw	**D 10 x L 30**	Calcium Phosphate - Polymer
11CPVI0720	Composite Interference Screw	**D 7 x L 20**	Calcium Phosphate - Polymer
11CPVI0820	Composite Interference Screw	**D 8 x L 20**	Calcium Phosphate - Polymer
11CPVI0920	Composite Interference Screw	**D 9 x L 20**	Calcium Phosphate - Polymer
12CPVI1025	Composite Interference Screw	**D 10 x L 25**	Calcium Phosphate - Polymer
15CPVI1135	Composite Interference Screw	**D 11 x L 35**	Calcium Phosphate - Polymer
15CPVI1235	Composite Interference Screw	**D 12 x L 35**	Calcium Phosphate - Polymer
13PVI0720	Polylactic Interference Screw	**D 7 x L 20**	Polymer
13PVI0725	Polylactic Interference Screw	**D 7x L 25**	Polymer
13PVI0730	Polylactic Interference Screw	**D 7 x L 30**	Polymer
13PVI0820	Polylactic Interference Screw	**D 8 x L 20**	Polymer
13PVI0825	Polylactic Interference Screw	**D 8 x L 25**	Polymer
13PVI0830	Polylactic Interference Screw	**D 8 x L 30**	Polymer
13PVI0920	Polylactic Interference Screw	**D 9 x L 20**	Polymer
13PVI0925	Polylactic Interference Screw	**D 9 x L 25**	Polymer
13PVI0930	Polylactic Interference Screw	**D 9 x L 30**	Polymer

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 032283 0057 Rev. 00

13PVI1025	Polylactic Interference Screw	**D 10 x L 25**	Polymer
13PVI1030	Polylactic Interference Screw	**D 10 x L 30**	Polymer
15PVI1135	Polylactic Interference Screw	**D 11 x L 35**	Polymer
15PVI1235	Polylactic Interference Screw	**D 12 x L 35**	Polymer
121-10-0125	Composite Interference Screw	**D 10 x L 25**	Calcium Phosphate - Polymer
121-10-0130	Composite Interference Screw	**D 10 x L 30**	Calcium Phosphate - Polymer
121-10-0720	Composite Interference Screw	**D 7 x L 20**	Calcium Phosphate - Polymer
121-10-0725	Composite Interference Screw	**D 7x L 25**	Calcium Phosphate - Polymer
121-10-0730	Composite Interference Screw	**D 7 x L 30**	Calcium Phosphate - Polymer
121-10-0820	Composite Interference Screw	**D 8 x L 20**	Calcium Phosphate - Polymer
121-10-0825	Composite Interference Screw	**D 8 x L 25**	Calcium Phosphate - Polymer
121-10-0830	Composite Interference Screw	**D 8 x L 30**	Calcium Phosphate - Polymer
121-10-0920	Composite Interference Screw	**D 9 x L 20**	Calcium Phosphate - Polymer
121-10-0925	Composite Interference Screw	**D 9 x L 25**	Calcium Phosphate - Polymer
121-10-0930	Composite Interference Screw	**D 9 x L 30**	Calcium Phosphate - Polymer
121-10-1135	Composite Interference Screw	**D 11 x L 35**	Calcium Phosphate - Polymer
121-10-1235	Composite Interference Screw	**D 12 x L 35**	Calcium Phosphate - Polymer
MX08CPVI0725	Composite Interference Screw	**D 7x L 25**	Calcium Phosphate - Polymer
MX08CPVI0730	Composite Interference Screw	**D 7 x L 30**	Calcium Phosphate - Polymer
MX08CPVI0825	Composite Interference Screw	**D 8 x L 25**	Calcium Phosphate - Polymer
MX08CPVI0830	Composite Interference Screw	**D 8 x L 30**	Calcium Phosphate - Polymer
MX08CPVI0925	Composite Interference Screw	**D 9 x L 25**	Calcium Phosphate - Polymer
MX08CPVI0930	Composite Interference Screw	**D 9 x L 30**	Calcium Phosphate - Polymer
MX08CPVI1030	Composite Interference Screw	**D 10 x L 30**	Calcium Phosphate - Polymer
MX11CPVI0720	Composite Interference Screw	**D 7 x L 20**	Calcium Phosphate - Polymer
MX11CPVI0820	Composite Interference Screw	**D 8 x L 20**	Calcium Phosphate - Polymer
MX11CPVI0920	Composite Interference Screw	**D 9 x L 20**	Calcium Phosphate - Polymer
MX12CPVI1025	Composite Interference Screw	**D 10 x L 25**	Calcium Phosphate - Polymer
MX15CPVI1135	Composite Interference Screw	**D 11 x L 35**	Calcium Phosphate - Polymer
MX15CPVI1235	Composite Interference Screw	**D 12 x L 35**	Calcium Phosphate - Polymer

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EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 032283 0057 Rev. 00

1-0402702	Polylactic Interference Screw	**D 10 x L 25**	Polymer
1-0402703	Polylactic Interference Screw	**D 10 x L 30**	Polymer
1-0402714	Polylactic Interference Screw	**D 11 x L 35**	Polymer
1-0402724	Polylactic Interference Screw	**D 12 x L 35**	Polymer
1-0402771	Polylactic Interference Screw	**D 7 x L 20**	Polymer
1-0402772	Polylactic Interference Screw	**D 7x L 25**	Polymer
1-0402773	Polylactic Interference Screw	**D 7 x L 30**	Polymer
1-0402781	Polylactic Interference Screw	**D 8 x L 20**	Polymer
1-0402782	Polylactic Interference Screw	**D 8 x L 25**	Polymer
1-0402783	Polylactic Interference Screw	**D 8 x L 30**	Polymer
1-0402791	Polylactic Interference Screw	**D 9 x L 20**	Polymer
1-0402792	Polylactic Interference Screw	**D 9 x L 25**	Polymer
1-0402793	Polylactic Interference Screw	**D 9 x L 30**	Polymer
1-0401004	Composite Interference Screw	**D 11 x L 35**	Calcium Phosphate - Polymer
1-0401012	Composite Interference Screw	**D 10 x L 25**	Calcium Phosphate - Polymer
1-0401013	Composite Interference Screw	**D 10 x L 30**	Calcium Phosphate - Polymer
1-0401024	Composite Interference Screw	**D 12 x L 35**	Calcium Phosphate - Polymer
1-0401071	Composite Interference Screw	**D 7 x L 20**	Calcium Phosphate - Polymer
1-0401072	Composite Interference Screw	**D 7x L 25**	Calcium Phosphate - Polymer
1-0401073	Composite Interference Screw	**D 7 x L 30**	Calcium Phosphate - Polymer
1-0401081	Composite Interference Screw	**D 8 x L 20**	Calcium Phosphate - Polymer
1-0401082	Composite Interference Screw	**D 8 x L 25**	Calcium Phosphate - Polymer
1-0401083	Composite Interference Screw	**D 8 x L 30**	Calcium Phosphate - Polymer
1-0401091	Composite Interference Screw	**D 9 x L 20**	Calcium Phosphate - Polymer
1-0401092	Composite Interference Screw	**D 9 x L 25**	Calcium Phosphate - Polymer
1-0401093	Composite Interference Screw	**D 9 x L 30**	Calcium Phosphate - Polymer
LE08CPVI0725	Composite Interference Screw	**D 7x L 25**	Calcium Phosphate - Polymer
LE08CPVI0730	Composite Interference Screw	**D 7 x L 30**	Calcium Phosphate - Polymer
LE08CPVI0825	Composite Interference Screw	**D 8 x L 25**	Calcium Phosphate - Polymer
LE08CPVI0830	Composite Interference Screw	**D 8 x L 30**	Calcium Phosphate - Polymer

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EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 032283 0057 Rev. 00

LE08CPVI0925	Composite Interference Screw	**D 9 x L 25**	Calcium Phosphate - Polymer
LE08CPVI0930	Composite Interference Screw	**D 9 x L 30**	Calcium Phosphate - Polymer
LE08CPVI1030	Composite Interference Screw	**D 10 x L 30**	Calcium Phosphate - Polymer
LE11CPVI0720	Composite Interference Screw	**D 7 x L 20**	Calcium Phosphate - Polymer
LE11CPVI0820	Composite Interference Screw	**D 8 x L 20**	Calcium Phosphate - Polymer
LE11CPVI0920	Composite Interference Screw	**D 9 x L 20**	Calcium Phosphate - Polymer
LE12CPVI1025	Composite Interference Screw	**D 10 x L 25**	Calcium Phosphate - Polymer
LE15CPVI1135	Composite Interference Screw	**D 11 x L 35**	Calcium Phosphate - Polymer
LE15CPVI1235	Composite Interference Screw	**D 12 x L 35**	Calcium Phosphate - Polymer
LE13PVI0720	Polylactic Interference Screw	**D 7 x L 20**	Polymer
LE13PVI0725	Polylactic Interference Screw	**D 7x L 25**	Polymer
LE13PVI0730	Polylactic Interference Screw	**D 7 x L 30**	Polymer
LE13PVI0820	Polylactic Interference Screw	**D 8 x L 20**	Polymer
LE13PVI0825	Polylactic Interference Screw	**D 8 x L 25**	Polymer
LE13PVI0830	Polylactic Interference Screw	**D 8 x L 30**	Polymer
LE13PVI0920	Polylactic Interference Screw	**D 9 x L 20**	Polymer
LE13PVI0925	Polylactic Interference Screw	**D 9 x L 25**	Polymer
LE13PVI0930	Polylactic Interference Screw	**D 9 x L 30**	Polymer
LE13PVI1025	Polylactic Interference Screw	**D 10 x L 25**	Polymer
LE13PVI1030	Polylactic Interference Screw	**D 10 x L 30**	Polymer
LE15PVI1135	Polylactic Interference Screw	**D 11 x L 35**	Polymer
LE15PVI1235	Polylactic Interference Screw	**D 12 x L 35**	Polymer

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EC Certificate Full Quality Assurance System: Certificate/Certificat: FR19/81843462

The management system of / Le système de management de

COUSIN BIOTECH s.a.s

8, Rue de l'Abbé Bonpain, 59117 Wervicq-Sud, 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)
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 09 March 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 31 October 1996
and first certified by SGS Belgium NV since 16 December 2019

Ce certificat est valable du 09 mars 2020 au 24 mai 2024
et reste valide sous condition d'audits de surveillance satisfaisants.
Version 2. Certifié depuis 31 octobre 1996
et initialement certifié par SGS Belgium NV depuis 16 December 2019

Certification is based on reports numbered / La certification est basée sur les rapports référence FR/MD 06953

This is a multi-site certification.
Additional site details are listed on subsequent pages.

Ceci concerne une certification multi site.
La liste des sites additionnels est mentionnée dans les pages suivantes.

Authorised by / Autorisé par

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

COUSIN BIOTECH s.a.s

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)
Dispositifs médicaux, Annexe II (section 4 exclue)

Issue / Version 2

For the following products / Pour les produits suivants

Disposable sterile Surgical instruments for the setup of the implants (always provided in a set with the implants).
Non-sterile trial prosthesis for spinal and visceral surgeries;
Sterile Extraperitoneal non-resorbable parietal reinforcement implants;
Sterile intraperitoneal non-resorbable parietal reinforcement implants;
Sterile Adjustable gastric banding
Sterile spinal dynamic posterior stabilization devices;
Sterile devices for the interspinous space (with spinous support or with laminar support) ;
Sterile urogenital implants (Suburethral support tape and prolapse implants) ;
Sterile non resorbable Articular ligaments
Sterile Cortical fixation devices;
Sterile anchor devices tendinous and ligament reinforcement
Sterile ligament system for spinal correction and stabilization;
Sterile intervertebral prosthesis;
Sterile BIOMESH® N3 and N3L Dura Mater Substitute Neurological Patches;
Sterile Adhesix™ Mesh Adhesive Parietal Reinforcement Implants.
Sterile Biomesh® Semi Resorbable Reinforcement Meshes, Semi Resorbable Plugs and Films. – comprising Sterile 4DDOME® devices;
Sterile 4DMESH / Biomesh® SR devices;
Sterile Biomesh® C.A.B.S. Air® SR devices and sterile 4D VENTRAL® devices;
Sterile ADHESIX®-BIORING® , T-BAND® and SLIMBAND™ Adjustable Gastric Bands (with adhesive mesh support for the implantable port)

Class I Sterile: "Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions"

Sterile and disposable tensioner ancillaries for the placement of Ligament System For Spinal Stabilization

COUSIN BIOTECH s.a.s

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)
Dispositifs médicaux, Annexe II (section 4 exclue)

Issue / Version 2

For the following products / Pour les produits suivants

Instruments chirurgicaux stériles à usage unique pour la mise en place d'implants (fournis en kit avec l'implant). ;
Prothèses d'essai non-stériles pour les chirurgies rachidienne et viscérale ;
Implants stériles de renforcement pariétal extrapéritonéale non résorbables ;
Implants stériles de renforcement pariétal intrapéritonéale non résorbables ;
Anneaux gastriques ajustables stériles
Dispositifs rachidiens stériles de stabilisation postérieures dynamiques ;
Dispositifs stériles pour l'espace inter épineux (avec appui épineux ou avec appui lamaire);
Implants urogénitaux stériles (Bandelettes de support sous urétrales et Implants pour le traitement du prolapsus) ;
Ligaments articulaires non résorbables stériles et dispositif de fixation cortical;
Dispositifs d'ancrage stériles pour le renforcement ligamentaire et tendineux ;
Système ligamentaire stérile pour stabilisation rachidienne ;
Prothèses intervertébrales stériles
Patchs neurologiques stériles Biomesh® N3 et N3L, Substituts de la dure mère crânienne et spinale ;
Adhesix® Implants de renforcement pariétal adhésifs stériles ;
Plaques, Plugs et Films semi résorbables stériles : 4DMESH®, 4DDOME®, 4D VENTRAL® and Biomesh® CA.B.S.'Air SR®, Implant de renforcement pariétal semi résorbable;
Anneau gastrique ajustable stérile avec système de fixation adhésif de la chambre implantable Adhesix® Bioring®.

Classe I Stérile – « Produits mis sur le marché à l'état stérile, limité aux seuls aspects de la fabrication liés à l'obtention et au maintien de l'état stérile »

Dispositifs médicaux non implantables stériles pour la chirurgie rachidienne comprenant : Système ligamentaire pour stabilisation rachidienne

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.

Lorsque le champ d'application ci-dessus comprend un ou plusieurs dispositifs médicaux de classe III, un certificat EC Design Examination Certificate valide, conformément à l'annexe II (section 4), est obligatoire pour chaque dispositif, en addition du présent certificat, pour la mise sur le marché du dispositif.

Additional facilities/Sites additionnels

Allée des Roses, 59117 Wervicq-Sud, France

Certificate FR96/8325

The management system of

COUSIN BIOTECH s.a.s

8, Rue de l'Abbé Bonpain, 59117 Wervicq-Sud, France

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

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

This certificate is valid from 05 September 2019 until 03 May 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 02 May 2022
Issue 31. Certified since 31 October 1996

Expiry date of previous certificate: 03 May 2019
End date of last recertification audit: 25 April 2019

This is a multi-site certification.
Additional site details are listed on subsequent pages.

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

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

HC SGS 13485 2016 0118 M3

COUSIN BIOTECH s.a.s

ISO 13485:2016
EN ISO 13485:2016

Issue 31

Detailed scope

Design, manufacture and sales of implantable medical devices for visceral, orthopedic, vascular, neurological, gynecological and urological surgery comprising:

Non-resorbable parietal reinforcement sterile implants (Abdominal plug and meshes and reinforcement plug and meshes abdominal wall); Sterile Adjustable gastric banding; Sterile Non resorbable articular ligaments; Sterile Anchor devices; Sterile Devices for the interspinous space (with spinous support or with laminar support); Sterile Intervertebral prostheses; Sterile Urogenital implants (Suburethral support tape and Implant for the treatment of prolapse); Non-sterile Trial Prosthesis for spinal and visceral surgeries; Sterile ligament system for spine stabilization;

Sterile spinal dynamic posterior stabilization devices.

Sterile Adhesix® Parietal Reinforcement Meshes with one adhesive side; Sterile Semi-Resorbable Meshes, Plugs and Films: Biomesh® SR, 4DDOME®, Biomesh® CA.B.S.'Air ® SR, Semi Resorbable Reinforcement Parietal Implant; Sterile Biomesh® COH and Biomesh® COL wall reinforcement meshes coated with porcine collagen; Sterile Neurological Patches: Biomesh™ N3 and N3L, Cranial and Spinal Dura Mater Substitutes; Sterile Adjustable gastric banding with adhesive mesh support for the implantable port - Adhesix® - Bioring®.

Design, manufacture and sales of sterile non-implantable medical devices for visceral, gynecological and urological surgery comprising: Ligament system for spinal stabilization

Contract manufacturing of implantable medical devices for orthopaedic, general, vascular and neurological surgery.

UKAS MANAGEMENT SYSTEMS
0005

COUSIN BIOTECH s.a.s

ISO 13485:2016
EN ISO 13485:2016

Issue 31

Detailed scope

Conception, fabrication et commercialisation de dispositifs médicaux implantables pour la chirurgie viscérale, orthopédique, vasculaire, neurologique, gynécologique et urologique, comprenant: Implants stériles de renforcement pariétal non résorbables (plaques et plugs abdominaux et plaques et plugs de renforcement de la paroi abdominale); Anneaux gastriques ajustables stériles; Ligaments articulaires non résorbables stériles; Dispositifs d'ancrage stériles; Dispositifs stériles pour l'espace inter-épineux (avec appui épineux ou avec appui lamaire); Prothèses intervertébrales stériles; Implants urogénitaux stériles (Bandelettes de support sous-urétrales et Implants pour le traitement du prolapsus); Prothèses d'essai non-stériles pour les chirurgies rachidienne et viscérale; Système ligamentaire stérile pour stabilisation rachidienne; Dispositifs rachidiens stériles de stabilisation postérieure dynamique. Adhesix® Implants de renforcement pariétal adhésifs stériles; Plaques, Plugs et Films semi résorbables stériles: 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; Patchs neurologiques stériles: Biomesh™ N3 et N3L, Substituts de la dure mère crânienne et spinale; Anneau gastrique ajustable stérile avec système de fixation adhésif de la chambre implantable - Adhesix® - Bioring®.

Conception, fabrication et commercialisation de dispositifs médicaux non-implantables stériles pour la chirurgie viscérale, gynécologique et urologique, comprenant : Système ligamentaire pour stabilisation rachidienne.

Fabrication en sous-traitance de dispositifs médicaux implantables pour la chirurgie orthopédique, générale, vasculaire et neurologique.

Additional facilities

Allée des roses, 59117 Wervicq-Sud, France

UKAS MANAGEMENT SYSTEMS
0005

DECLARATION DE CONFORMITE CE	EC DECLARATION OF CONFORMITY	EC KONFORMITÄTS-ERKLÄRUNG	DICHIARAZIONE DI CONFORMITA CE	DECLARACION DE CONFORMIDAD CE	DECLARAÇÃO DE CONFORMIDADE CE	CONFORMITEITS VERKLARING CE	ΔΉΛΩΣΗ ΕΚ ΤΗΣ ΣΥΜΜΌΡΦΩΣΗΣ

COUSIN BIOTECH S.A.S

8, rue de l'Abbé Bonpain 59117 Wervicq-Sud FRANCE

Déclarons, sous notre seule responsabilité de fabricant, que les dispositifs cités ci-dessous	Declare, under our sole responsibility as manufacturer, that devces mentioned below	Der Unterzeichnete erklärt im Namen der Firma Daβ die Produkte des Herstelles	Il sottoschritto dichiara in nome di Che i prodotti del fabricante	Por la presente, el abajo firmante declara en nombre de la empresa Que las productos del fabricante	O signatário abaixo declara ao nome da empresa Que os produtos do fabricante	De ondertekende verklaart in name van dat de producten van de fabrikant	Ο υπογεγραμμένος δηλώνει εξ ονόματος Ότι το προϊόν παραχθέν κοντά
Référence	Reference	Katalog – Nummer	Codici	Referencias	Referências	Referentie	Αναφορά

Dispositifs d'ancrage stériles
Sterile Anchor devices

OCBGEFX15U - OCBGEFX20U - OCBGEFX25U - OCBGEFX30U - OCBGEFX35U - OCBGEFX40U - OCBGEPLB1U - OCBGEFRB1U
COMETE: OAMGEFX15U - OAMGEFX20U - OAMGEFX25U - OAMGEFX30U - OAMGEFX35U - OAMGEFX40U
COMETE CONTROL: OAMGEFRC1U COMETE EXTRA PLATE: OAMGEPLA1U
Continuous One: OBOGEFX15U - OBOGEFX20U - OBOGEFX25U - OBOGEFX30U - OBOGEFX35U - OBOGEFX40U
Adjustable One: OBOGEFRB1U Extension One: OBOGEPLB1U
BOTAO: 607MBEND15 - 607MBEND20 - 607MBEND25 - 607MBEND30 - 607MBEND35 - 607MBEND40 - 607MBENDXT
CoronButton™ Fixed: B-EBF-1215 - B-EBF-1220 - B-EBF-1225 - B-EBF-1230 - B-EBF-1235 - B-BEF-1240 CoronButton™ Adjustable: B-EBA-1200
B-EBE-2000
Mectaloop: 05.05.0080 - 05.05.0081 - 05.05.0082 - 05.05.0083 - 05.05.0084 - 05.05.0085 - 05.05.0086

(*) UDI-DI codes are listed in the Table below.

Sont des Dispositifs Médicaux de classe IIb	are Medical Devices of class IIb	Sind Klasse Is Medizin Produkte IIb	Sono dispositivi medici della classe IIb	Son dispositivos Medicos de classe IIb	Sao dispositivos medicos de classe IIb	Medische Hulpmiddelen zijn van klasse IIb	είναι ιατρικές συσκευές του classe IIb

Rule(s) applied for classification : According to the annex IX §III point 2.4 rule 8 of the classification criteria of the Directive 93/42/EEC

Conformes à	In conformance with	Entsprechend der	Conformi alla	Satisfacen las disposiciones pertinentes siguientes	Satisfazen as disposiçoes seguintes	In overeenstemming zijn met	Στην προσαρμογή με

Directive 93/42/CEE relative aux dispositifs médicaux, consolidée avec la Directive 2007/47/CE
Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC

Conformity Assessment Procedure:
Annexe II de la Directive Européenne 93/42/CEE (section 4 exclue) et au livre Vbis du Code de la Santé Publique
Annex II of European Directive (MDD) 93/42/EEC (excluding section 4) and the book Vbis of the Public Health Code

Règlement (UE) n°*207/2012* de la Commission du 9 mars 2012 relatif aux instructions d'emploi électroniques des dispositifs médicaux
Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices

Et vérifiés par l'organisme notifié	And verified by notified body	Und von der zuständigen Behörde überprüft	E verificati da un organismo notificato	Y verificados por el organismo notificado	E verificados por o organismo notificado	En gecontroleerd door et erkende organisme	Και ελεγγμένος από το ειδοποιημένο σώμα

SGS Belgium NV
Noorderlaan 87, BE-2030 Antwerpen, Belgium
Notified Body No: **1639**

EC Certificate Full Quality Assurance System	***Certificate FR19/81843462***	*Issue 2*	**Certificate valid from**	***9th March 2020***	**Until**	**24th May 2024**

Directeur Affaires Réglementaires	Regulatory Affairs Director	Regulatory Affairs Director	Direttore Affari Regolamentari	Director asuntos reglamentarios	Negócio autorizado responsável	Directeur Regulatory Affairs	Διευθυντής Ρυθμιστικών Θεμάτων

Wervicq-Sud, on 13/03/2020 , F.PELLETIER

OAMGEFCR1U	UDI-DI: 03760185575874
OAMGEPLA1U	UDI-DI: 03760185573778
OAMGEFX15U	UDI-DI: 03760185573719
OAMGEFX20U	UDI-DI: 03760185573726
OAMGEFX25U	UDI-DI: 03760185573733
OAMGEFX30U	UDI-DI: 03760185573740
OAMGEFX35U	UDI-DI: 03760185573757
OAMGEFX40U	UDI-DI: 03760185573764
OCBGEFRB1U	UDI-DI: 03760185575393
OCBGEPLB1U	UDI-DI: 03760185575416
OCBGEFX15U	UDI-DI: 03760185573832
OCBGEFX20U	UDI-DI: 03760185573849
OCBGEFX25U	UDI-DI: 03760185573856
OCBGEFX30U	UDI-DI: 03760185573863
OCBGEFX35U	UDI-DI: 03760185573870
OCBGEFX40U	UDI-DI: 03760185573887
OBOGEFX15U	UDI-DI: 03760185576420
OBOGEFX20U	UDI-DI: 03760185576437
OBOGEFX25U	UDI-DI: 03760185576444
OBOGEFX30U	UDI-DI: 03760185576451
OBOGEFX35U	UDI-DI: 03760185576468
OBOGEFX40U	UDI-DI: 03760185576475
OBOGEFRB1U	UDI-DI: 03760185576413
OBOGEPLB1U	UDI-DI: 03760185576482
607MBEND15	UDI-DI: 03760185576345
607MBEND20	UDI-DI: 03760185576352
607MBEND25	UDI-DI: 03760185576369
607MBEND30	UDI-DI: 03760185576376
607MBEND35	UDI-DI: 03760185576383
607MBEND40	UDI-DI: 03760185576390
607MBENDXT	UDI-DI: 03760185575416
B-EBF-1215	UDI-DI: 03760185576512
B-EBF-1220	UDI-DI: 03760185576529
B-EBF-1225	UDI-DI: 03760185576536
B-EBF-1230	UDI-DI: 03760185576543
B-EBF-1235	UDI-DI: 03760185576550
B-EBF-1240	UDI-DI: 03760185576567
B-EBA-1200	UDI-DI: 03760185576574
B-EBE-2000	UDI-DI: 03760185576505

05.05.0080	UDI-DI: 03760185576581
05.05.0081	UDI-DI: 03760185576588
05.05.0082	UDI-DI: 03760185576595
05.05.0083	UDI-DI: 03760185576602
05.05.0084	UDI-DI: 03760185576609
05.05.0085	UDI-DI: 03760185576616
05.05.0086	UDI-DI: 03760185576623

Biomatlante
Biologics Solutions

BIOMATLANTE 5, Rue Edouard Belin ZA les Quatre Nations 44360 Vigneux de Bretagne	IMPRIMES **EC DECLARATION OF CONFORMITY**	**IM5.22-EN** Version 2 Page : 1/2

Manufacturer: Biomatlante
ZA Les Quatre Nations
5 Rue Edouard Belin
44360 Vigneux de Bretagne
France

Notify Body: TÜV SÜD Product Service GmbH
Ridlerstraβe 65
80339 Munich
Allemagne
Identification N°: 0123

Product Category: Resorbable Fixation Systems

Product Articles Numbers: See Attachments

We, Biomatlante, declare under our sole responsibility that the above mentioned products are compliant to the dispositions of the following EC Directive and to the provisions transposing this Directive into the code of the French Public Health.

Directive: Directive 93/42/CEE
Classification: Class III

Assessment of Conformity: Annex II
CE Certificates: *Annex II.3 :* G1 16 05 32283 045
Annex II.4 : G7 032283 0057 Rev. 00

Expiry Date of Declaration of Conformity: 6 December 2022

These devices are manufactured in the European Union.

On: 14 October 2019
Place: Vigneux de Bretagne

Name of the authorized person: Mme Nancy TRICHEREAU
Function of the authorized person: Quality and Regulatory Affairs Manager

Signature :

Product Category : Resorbable Fixation Systems

Trade name	Articles Numbers	Designations	Date of the 1st EC Market was affixed
ECLIPSE® BCP	1-0401004	Composite Interference screw 11x35mm	19/11/2015
ECLIPSE® BCP	1-0401012	Composite Interference screw 10x25mm	23/12/2011
ECLIPSE® BCP	1-0401013	Composite Interference screw 10x30mm	23/12/2011
ECLIPSE® BCP	1-0401024	Composite Interference screw 12x35mm	19/11/2015
ECLIPSE® BCP	1-0401071	Composite Interference screw 7x20mm	23/12/2011
ECLIPSE® BCP	1-0401072	Composite Interference screw 7x25mm	23/12/2011
ECLIPSE® BCP	1-0401073	Composite Interference screw 7x30mm	23/12/2011
ECLIPSE® BCP	1-0401081	Composite Interference screw 8x20mm	23/12/2011
ECLIPSE® BCP	1-0401082	Composite Interference screw 8x25mm	23/12/2011
ECLIPSE® BCP	1-0401083	Composite Interference screw 8x30mm	23/12/2011
ECLIPSE® BCP	1-0401091	Composite Interference screw 9x20mm	23/12/2011
ECLIPSE® BCP	1-0401092	Composite Interference screw 9x25mm	23/12/2011
ECLIPSE® BCP	1-0401093	Composite Interference screw 9x30mm	23/12/2011
ECLIPSE® Profil	1-0402702	Polylactic Interference screw 10x25mm	19/07/2013
ECLIPSE® Profil	1-0402703	Polylactic Interference screw 10x30mm	19/07/2013
ECLIPSE® Profil	1-0402714	Polylactic Interference screw 11x35mm	19/11/2015
ECLIPSE® Profil	1-0402724	Polylactic Interference screw 12x35mm	19/11/2015
ECLIPSE® Profil	1-0402771	Polylactic Interference screw 7x20mm	19/07/2013
ECLIPSE® Profil	1-0402772	Polylactic Interference screw 7x25mm	19/07/2013
ECLIPSE® Profil	1-0402773	Polylactic Interference screw 7x30mm	19/07/2013
ECLIPSE® Profil	1-0402781	Polylactic Interference screw 8x20mm	19/07/2013
ECLIPSE® Profil	1-0402782	Polylactic Interference screw 8x25mm	19/07/2013
ECLIPSE® Profil	1-0402783	Polylactic Interference screw 8x30mm	19/07/2013
ECLIPSE® Profil	1-0402791	Polylactic Interference screw 9x20mm	19/07/2013
ECLIPSE® Profil	1-0402792	Polylactic Interference screw 9x25mm	19/07/2013
ECLIPSE® Profil	1-0402793	Polylactic Interference screw 9x30mm	19/07/2013

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 032283 0058 Rev. 02

Certificate Holder: **Biomatlante SA**
ZA les Quatre Nations
5, Rue Edouard Belin
44360 Vigneux de Bretagne
FRANCE

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Calcium Phosphate, Bone Substitutes and Activity of Cleaning and Packaging of Medical Devices Sterile or Non-Sterile; Collagen Based Medical Devices, Polymer and Composites Implants with Associated Instruments and Calcium Phosphate Injectable Implants**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA. See attachment page for listing of specific regulatory requirements**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **49-371-0719**

Effective Date: **2019-02-05**

Expiry Date: **2022-02-04**

Date of Issue: 2019-09-17

Dawn Tibodeau

(Dawn M. Tibodeau)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 032283 0058 Rev. 02

Regulatory Requirements:

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Facility(ies):

Biomatlante SA
ZA les Quatre Nations, 5, Rue Edouard Belin, 44360 Vigneux de Bretagne, FRANCE

Biomatlante SA
Pôle Bio-Ouest, Rue du Moulin de la Rousselière, 44800 Saint Herblain, FRANCE

Date of Issue: 2019-09-17

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MEDICAL DEVICE SINGLE AUDIT PROGRAM

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CERTIFICATE

No. QS6 032283 0058 Rev. 02

Facility Scopes:

Biomatlante SA
ZA les Quatre Nations, 5, Rue Edouard Belin, 44360 Vigneux de Bretagne, FRANCE

Design and Development, Production and Distribution of Calcium Phosphate, Bone Substitutes and Activity of Cleaning and Packaging of Medical Devices Sterile or Non-Sterile; Collagen Based Medical Devices, Polymer and Composites Implants with Associated Instruments and Calcium Phosphate Injectable Implants
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Pôle Bio-Ouest, Rue du Moulin de la Rousselière, 44800 Saint Herblain, FRANCE

Design and Development, Production and Distribution of Calcium Phosphate, Bone Substitutes; Collagen Based Medical Devices, Polymer and Composites Implants with Associated Instruments and Calcium Phosphate Injectable Implants
DUNS No: 26-125-5300

Date of Issue: 2019-09-17

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