BIOTECH DENTAL

QUALITY CERTIFICATE

Here, your dental surgeon trusts to the french Biotech Dental dental implant system.

"The Biotech Dental, key player in the health sector, is positioned among the leaders in the implantology and dental prosthesis market. With nearly 35 years of experience in the design and manufacture of dental implants, we are committed to providing ever more innovative and scientifically proven products.

The only dental manufacturer to benefit from the Origine France Garantie, des labels French Tech et French Fab, Biotech Dental is proud to embody the medical know-how « **100% Made in France*** ».

garantie À VIE ***

The various quality certifications granted by the most recognized organizations are proof of the daily demands that we place on R&D, our industrial processes and controls. With more than 2.5 million implants placed worldwide, we guarantee dentists complete solutions so that patients can benefit from the bests treatments."

Philippe Véran
CEO

GMED GROUPE LNE

ATTESTATION / *CERTIFICATE* N° 30154 rev. 21
Délivrée à Paris le 07 mai 2021
Issued in Paris on May 7th, 2021

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
ANNEXE II exclusif à la point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*
BIOTECH DENTAL S.A.S.
305 Allées de Craponne
13300 SALON DE PROVENCE FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*
Implants dentaires stériles avec leurs vis de couverture et de cicatrisation.
Composants prothétiques non stériles pour la pose d'implants dentaires.
Système de fixation non stérile pour greffons osseux ou membranes.
Dispositifs ancillaires non stériles, comprenant les instruments rotatifs pour la chirurgie dentaire.
Sterile dental implants with their cover screws and healing screws.
Non sterile prosthetic components for the fitting of dental implants.
Non sterile fixation system for bone grafts or membranes.
Non sterile ancillary devices, including rotating dental surgical instruments.
Voir document complémentaire GMED / See GMED additional document
n° 37542

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P177199 / P600948, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P177199 / P600948, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

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* : **May 7th, 2021 (included)**
Valable jusqu'au / *Expiry date* : **May 26th, 2024 (included)**

On behalf of the President
Béatrice LYS
Technical Director

GMED - 30154 rev. 21
Modifie le certificat 30154-20

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

CLEAN IMPLANT FOUNDATION

TRUSTED QUALITY 2021-2023

This certificate is awarded to
BIOTECH DENTAL
for the dental implant
Kontact S

The aforesaid implant complies with the CleanImplant Quality Mark Criteria 2021-2023
according to the consensus recommendation of the Scientific Advisory Board released September 2017.

Berlin, May 3rd, 2021

Prof. Jaber Mouhyi
CleanImplant Scientific Advisory Board

Prof. Hugo de Bruyn
CleanImplant Scientific Advisory Board

Dr. Dirk U. Duddeck
Managing Director CleanImplant Foundation

GMED GROUPE LNE

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 30159 rev. 4

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

BIOTECH DENTAL S.A.S.
305 Allées de Craponne
13300 SALON DE PROVENCE FRANCE

pour les activités
for the activities

Conception, développement, fabrication et commercialisation d'implants dentaires stériles avec leurs vis de couverture et de cicatrisation, de phases prothétiques et d'instruments associés non stériles pour usage dentaire. Distribution de dispositifs médicaux dédiés à la chirurgie dentaire incluant des moteurs et leur réparation.

Design, development, manufacturing and sales of sterile dental implants with their cover screws and healing screws, non sterile related prosthetic parts and non sterile instruments for dental use. Distribution of medical devices dedicated to dental surgery including motors and their repair.

réalisées sur le(s) site(s) de
performed on the location(s) of
305 Allées de Craponne
13300 SALON DE PROVENCE FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485 : 2016 - NF EN ISO 13485 : 2016

Début de validité / *Effective date* : **June 7th, 2021 (included)**
Valable jusqu'au / *Expiry date* : **June 8th, 2024 (included)**
Etabli le / *Issued on* : **June 7th, 2021**

On behalf of the President
Béatrice LYS
Technical Director

GMED N° 30159-4
Ce certificat est délivré selon les règles de certification GMED / *This certificate is issued according to the rules of GMED certification*

Renouvelle le certificat 30159-3

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

La FRENCH FAB

La FRENCH TECH

ORIGINE FRANCE GARANTIE

AFNOR Cert. 73017

FDA **

*Our implants are manufactured in our own production plant
**Kontact™ implants have received approval from the Food and Drug Administration (USA)
***This guarantee only applies in the context of the exclusive use of original Biotech Dental products, by an eligible and trained healthcare professional, in strict compliance with the recommendations and protocols recommended by the brand. For more information on this warranty, visit our website: www.biotech-dental.com