Global
ORTHOSYS
Commitment To Community

MAXILLOFACIAL IMPLANT ADVANCED KIT

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Certificate No. : CE-337

Certificate

OF COMPLIANCE

We hereby declare that the technical file of the product confirms with the requirement of Medical Devices Directive (MDD), Directive regulated by 93/42/EEC of June 1993.

Manufacturer: **GLOBAL ORTHOSYS**

Address : Plot No. - 130, Golden Green Industrial Park, Survey No. - 111, Khambha (Shapar) Rajkot - 360311, Gujarat, India

Products : Orthopaedic Implants & Instruments, Maxillofacial Implants & Instruments

The Certification body has performed an audit of the above product quality system covering design, manufacture and final inspection of the certified product. The Quality system has been assessed, approved and is subject to continuous surveillance according to the Medical Devices Directive (MDD), Directive regulated by 93/42/EEC.

Technical File Ref: **GOOTC01_Issue :- 01**

This Certificate is issued under the following Conditions:

1. It applies only to the quality system maintenance in the manufacture of above referenced models and it does not substitute the design or type examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed
3. The certificate validity is conditioned by positive results or Surveillance audits.

The CE Mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance Medical Devices Directive (MDD), Directive regulated by 93/42/EEC of June 1993. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Date of initial registration : Sep 28, 2021 — Certificate expiry : Sep 27, 2022

Date of this certificate : Sep 28, 2021 — Re-certification due : Sep 28, 2024

To check the status of the certificate, visit: "http://eac-council.org/validity"

(Authorized Signatory)

European Certification Council
101,Coltrand Grove Birmingham, B15 2BS,United Kingdom
www.eac-council.org
info@eac-council.org

*The Certificate of registration remains the property of European Accreditation and Certification Council. And shall be returned immediately upon request.

This is to Certify that the Management System of

GLOBAL ORTHOSYS

Plot No. 130, Golden Green Industrial Park, Survey No. 111, Khambha (Shapar), Rajkot - 360311, Gujarat, India

has been found to conform to the Medical Devices – Quality Management System standard:

ISO 13485:2018

This certificate is valid for the following scope of operations:

Manufacturing, Trading, Export and Import Designaing of Orthopedic Implants & Instrument, Maxillofacial Implants & Instrument and Related Products.

:: Certificate No :: IN54157H

Date of initial registration	Date of this Certificate	Surv. audit on or before / Certificate expiry	Recertification Due
28 September 2021	28 September 2021	27 September 2022	27 September 2024

This Certificate remains valid subject to satisfactory surveillance audits.

Director

Central Drugs Standard Control Organisation

Directorate General of Health Services

Ministry of Health & Family Welfare

(Medical Device & Diagnostic Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Phone No-011-23236965
Fax: 23236973
Dated : 11-OCT-2019

File No. : AZ/MD/2019/000057

M/s GLOBAL ORTHOSYS,
130 GOLDEN INDUSTRIAL
CITY,VILLAGE-KHAMBHA,
LODHIKA, Rajkot, Gujarat (India) - 360311
Telephone No.: 9898940227 FAX:
9427217406 Email:
bharat.sanofi@gmail.com

Sub:- Licence to manufacture for Sale or for Distribution of Class C or Class D medical devices in Form MD-9 under Medical Device Rules, 2017- regarding.

Sir,

Manufacturing licence No. MFG/MD/2019/000181 in Form MD-9 is hereby forwarded to you. This licence is subject to following conditions:

1. Licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority.
2. The licence holder shall inform the Central Licensing Authority of the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder
3. The licence holder shall obtain prior approval from the Central Licensing Authority, before any major change as specified in the Sixth Schedule is carried out and the Central Licensing Authority shall indicate its approval or rejection within forty five days and in case where no communication is received within the stipulated time from such Authority, such change shall be deemed to have been approved
4. The licence holder shall inform any minor change as specified in the Sixth Schedule to the Central Licensing Authority within a period of thirty days after such minor change take place
5. The licence holder shall carry out test of each batch of product manufactured prior to its release for compliance with specifications either in his own laboratory or in any other laboratory registered under sub-rule (3) of rule 83;