



MAXILLOFACIAL IMPLANT ADVANCED KIT

Certificate

Certificate of Compliance
 This is to certify that
GLOBAL ORTHOSYS
 at
 PLOT NO. 130, GOLDEN GREEN INDUSTRIAL PARK, SURVEY NO-111,
 KHAMBHA, SHAPAR, RAJKOT - 360311, GUJARAT, INDIA
 has been independently assessed by VRS and is compliant
 with the requirements of "Good Manufacturing Practice"

GMP
Good Manufacturing Practice
 For the following scope

**MANUFACTURING, TRADING, EXPORT, IMPORT AND DESIGNING
 OF ORTHOPAEDIC IMPLANTS & INSTRUMENT, MAXILLOFACIAL
 IMPLANTS & INSTRUMENT AND OTHER RELETED PRODUCTS**

Date of Certification : 18 February 2020 2nd Surveillance : 17 February 2023
 1st Surveillance : 17 February 2021 Re-certification Due on : 17 February 2023

Certificate No. : 2245/GMP/20

Authorised Signatory

VRS
 GLOBAL ORTHOSYS
 GMP CERTIFIED

ICMPL INTERNATIONAL
Certificate of Registration
 This is to Certify that the
 Quality Management System
 of
GLOBAL ORTHOSYS
 Plot No. - 130, Golden Green Industrial Park, Survey No. - 111,
 Khambha (Shapar) Rajkot - 360311, Gujarat, India
 Has been independently assessed and is compliant
 with the requirements of

ISO 9001:2015
 This Certificate is applicable to the following product or service ranges :

**"Manufacturing, Trading, Export and Import Designing of Orthopaedic Implants
 & Instrument, Maxillofacial Implants & Instrument and Related Products"**

Certificate No. : QM24G13377 Rev. 02
 Certified Since : Sep 10, 2018 Current Issue Date : Sep 08, 2024
 Expiry on : Sep 09, 2022 Date of Certification : Sep 10, 2024
 (Subject to the company maintaining its system to the required standard)
 *After Successful Completion of surveillance audits, New certificates shall be issued.

ICM Certification Manager

ICM Certification Private Limited
 # 6/82/62, 1st Floor, Tagore Park, Rajkot Road, Bhavnagar, New Pithla, JIMM4, India.
 E-mail: info@icmcertification.com / technical@icmcertification.com

*This Certificate is the Property of ICM Certification (P) Ltd. and shall be returned immediately on Request.

www.icmcertification.com

ECC
European Conformity Council Ltd.
Certificate
OF COMPLIANCE

Certificate No. : CE-337

We hereby declare that the technical file of the product conforms 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: **600701/Issue - 01**

This Certificate is based 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 rely on 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/>

Authorised Signatory

CE EA European Accreditation and Certification Council
 European Certification Council
 100 Colindale Avenue, Birmingham, B15 2RS, United Kingdom
www.eac-council.org info@eac-council.org

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

CERTIFICATE
 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 Designing of
 Orthopedic Implants & Instrument, Maxillofacial Implants
 & Instrument and Related Products.**

:: Certificate No :: **INS4157H**

Date of initial registration : 28 September 2021 Date of this Certificate : 28 September 2021 Start, valid on or before / Certificate expiry : 27 September 2024 Recertification Due : 27 September 2024

This Certificate remains valid subject to satisfactory surveillance audits.

Director

STAINCHLY MANAGEMENT AND SYSTEM SERVICES LIMITED
 142/97th Business Centre, 43, Madhav Hill Gate, Bhavnagar,
 Email: info@stainchly.com
 Phone : +91 792 402 3887
 Company Registered & Enlisted with Company Number: 1448868

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Device & Diagnostic Division)

FDA Bhavnagar, Kotla Road
 No. Delhi-10002
 Phone No-011-23236965
 Fax: 23236973
 Dated: 11-OCT-2019

File No. : AZ/MD/2019/000077

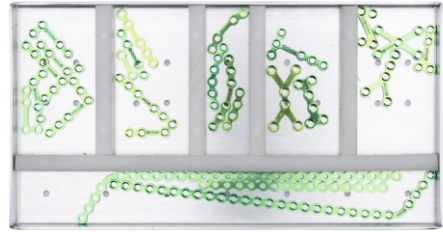
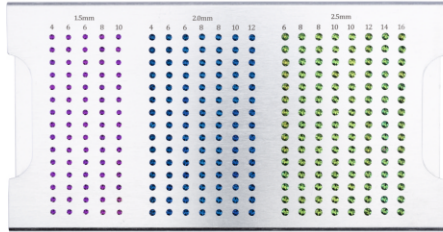
M/s GLOBAL ORTHOSYS,
 130 GOLDEN INDUSTRIAL
 CITY, VILLAGE-KHAMBHA,
 LODHIKA, Rajkot, Gujarat (India) - 360311
 Telephone No. : 9899540227 FAX:
 9427217406 Email:
 bharat.sanoji@gmail.com

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

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 its own laboratory or in any other laboratory registered under sub-rule (3) of rule 31.

MAXILLOFACIAL IMPLANT ADVANCED KIT





Corporate Office

“Shree”, New Balmukund Soc., Street No. 1, B/h. Copper Height, Opp. Raiya Munciple Chowk,
Sadhuvashwani Raod, Rajkot - 360 005. Mob. : +91 94272 17406, 98989 40227
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Manufacturing Unit

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