



OSTEOTOMES CHISELS GOUGES CURRETTES

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 2022
1st Surveillance : 17 February 2021 Re-certification Due on : 17 February 2023

Certificate No. : 2245/GMP/20

Authorised Signatory





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
Issued 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
4/82/62, 1st Floor, Tagore Park, Tagore Road, Bangalore, New Delhi-110044, 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

Certificate No. : CE-337

ECC
European
Certification
Council Ltd.

Certificate
OF COMPLIANCE

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 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 required.
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 2BS 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
Lotus Park Business Centre, 43, Madhav Hill Gate, Bhavnagar,
Gujarat, India. Gujarat-364001
Email: info@stainchly.com
Phone: +91 792 402 3887
Company Registered in England with Company Number 11488863




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

File No. : **AZ/MD/2019/000077**

M/s GLOBAL ORTHOSYS,
130 GOLDEN INDUSTRIAL
CITY, VILLAGE-KHAMBHA,
LODHKA, 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. MFGMD/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.

OSTEOTOMES-CHISELS-GOUGES-CURRENTTES

Fine Gouge



Category No.	Size
1124.01	2 mm
1124.02	3 mm
1124.03	4 mm
1124.04	6 mm
1124.05	8 mm
1124.06	10 mm

Tessier Osteotome
Straight



Category No.	Size
1125.01	5 mm
1125.02	10 mm
1125.03	15 mm
1125.04	20 mm

Fine Osteotome
Straight



Category No.	Size
1126.01	2 mm
1126.02	3 mm
1126.03	4 mm
1126.04	5 mm
1126.05	6 mm
1126.06	8 mm
1126.07	10 mm
1126.08	12 mm

Curved



Category No.	Size
1125.05	5 mm
1125.06	10 mm
1125.07	15 mm
1125.08	20 mm

Fine Osteotome
Straight



Category No.	Size
1126.01	2 mm
1126.02	3 mm
1126.03	4 mm
1126.04	5 mm
1126.05	6 mm
1126.06	8 mm
1126.07	10 mm
1126.08	12 mm

Curved



Category No.	Size
1126.09	2 mm
1126.10	3 mm
1126.11	4 mm
1126.12	5 mm
1126.13	6 mm
1126.14	8 mm
1126.15	10 mm
1126.16	12 mm

Fine Chisels



Category No.	Size
1127.01	2 mm
1127.02	3 mm
1127.03	4 mm
1127.04	5 mm
1127.05	6 mm
1127.06	8 mm
1127.07	10 mm
1127.08	12 mm

Cottle Osteotome
Half Moon



Category No.	Size
1128.01	8 mm
1128.02	10 mm

Nasal Septum Osteotome With Guard
"U" Shape



Category No.
1129

Nasal Chisel with Guard
Right & Left in Pair



Category No.	Size
1130.01	4 mm
1130.02	5 mm
1130.03	6 mm
1130.04	8 mm

Ramus Stripper



Category No.
1131

Pterigoidous Chisel



Category No.	Size
1132.01	6 mm
1132.02	8 mm
1132.03	10 mm
1132.04	12 mm

Bone Grafting Gouge with Fibre Handle



Category No.	Size
1133.01	2 mm
1133.02	4 mm
1133.03	6 mm
1133.04	8 mm
1133.05	10 mm

Volkman Bone Scoop - Double Ended



Category No.
1134

Lucas Currettes - Double Ended



Category No.
1135

Bone Scoop - Angled



Category No.
1136





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
Email : inquiry@globalorthosys.com, globalorthosys18@gmail.com

Manufacturing Unit

Plot No. 130, Survey No. 111, Golden Green Industrial Park, Khambha (Shapar) Rajkot - 360 311
Mob. : +91 98259 76543, Web. : www.globalorthosys.com