



RETRACTORS

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
 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
 # 4/82/62, 1st Floor, Tagore Park, Rajkot Road, Bhujana, 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
 Conformity
 Council Ltd.

**Certificate
 OF COMPLIANCE**

We hereby declare that the technical file of the product conforms with the requirements 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 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.

**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/2019/000077

**M/s GLOBAL ORTHOSYS,
 130 GOLDEN INDUSTRIAL
 CITY, VILLAGE-KHAMBHA,
 LODHKA, Rajkot, Gujarat (India) - 360311**
 Telephone No. : 9895940227 FAX:
 9427217406 Email:
 bharat.sanofi@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.

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
 145/146th Business Centre, 43, 34/34th Hill Gate, Bhujana,
 Email: info@stainchly.com
 Phone : +91 742 402 3887
 Company Registered in England with Company Number 11488663




RETRACTORS

McIndoe Retractor



Category No.
1046

Rayne Mandibular Retractor



Category No.
1047

Davis Double Ended Retractor



Category No.
1048

Chin Retractor



Category No.
1049

Forked Ramus Retractor



Category No.
1050

Channel Retractor



Category No.	Size
1051.01	8mm
1051.02	12mm

Channel Retractor
 Big Handle



Category No.
1051.03

Kilner Retractor Double Ended



Category No.	Size
1052.01	Small
1052.02	Medium
1052.03	Big

Kilner Nasal Retractor



Reference
1053

Aufricht Nasal Retractor



Solid

Category No.
1054.01

Aufricht Nasal & Double Hook Retractor



Category No.
1055

Fenestrated



Category No.
1054.02

Kilner Skin Retractor



Category No.
1056

Malleable Copper Retractor



Category No.	Size
1057.01	8"x10mm
1057.02	10"x15mm
1057.03	12"x20mm

Malleable S.S. Retractor



Category No.	Size
1058.01	8"x10mm
1058.02	10"x15mm
1058.03	12"x20mm

Austin Tissue Retractor



Regular

Category No.
1059.01



Half Moon

Category No.
1059.02



Forked

Category No.
1059.03

Desmarres Retractor



Category No.	Size
1062.01	Small
1062.02	Medium
1062.03	Big

Self Retaining Skin Retractor - "Alm's"

Small



Category No.
1060.01

Big



Category No.
1060.02

With Ratchet



Category No.
1060.03

Right Angle Retractor (Lengenback)



Category No.	Size
1061.01	Small 6 x 20mm



Category No.	Size
1061.02	Med. 10 x 30mm



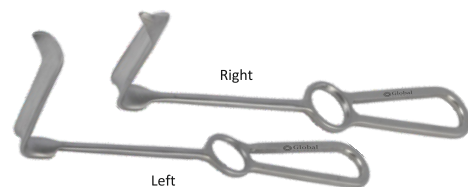
Category No.	Size
1061.03	Big 15 x 45mm

Condyle Retractor
 Double Ended



Category No.
1063

Condylar Neck Retractor- Right & Left in Pair



Category No.
1064

Lip & Cheek Retractor
Bishop



Category No.
1065

Kilner Alae Retractor



Category No.
1066

Volkman Retractor



Category No.
1067

Self Retaining Mastoid Retractor



Category No.	Size
1068.01	4"
1068.02	5"
1068.03	6"
1068.04	8"

Browne Lingual Flap Retractor



Category No.
1069

TMJ Retractor



Category No.	Size
1070	6mm x 10mm

Condylar Alveolar Retractor



Category No.
1071

Rowe Orbital Floor Retractor
 Right & Left in Pair



Category No.
1072

Superior Ramus Separater (Smith)



Category No.
1073

Universal Maxillary Spreader



Category No.
1074

Soft Tissue Retractor - Reverse Lengenback



Category No.
1075

Soft Tissue Retractor - Concave Blade



Category No.
1076

Minnesota Retractor



Category No.
1077

SENN Retractor



Category No.
1078

Sigmoid Notch Retractor



Category No.
1080



Intraoral Retractor - 3rd Molar



Category No.
1081

Plastic Cheek Retractor



Category No.	Size
1082.01	Small
1082.02	Medium
1082.03	Big

Ramus Retractor - Big Handle



Category No.	Size
1083.01	20 mm
1083.02	25 mm
1083.03	30 mm

Deaver Retractor



Category No.	Size
1084.01	1/2"
1084.02	1"





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