



## CLEFT LIP & PALATE INSTRUMENTS

# 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, 2022  
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, Bhubaneswar, New Delhi-110044, India.  
E-mail: [info@icmcertification.com](mailto:info@icmcertification.com) / [technical@icmcertification.com](mailto:technical@icmcertification.com)

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

[www.icmcertification.com](http://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 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 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](http://www.eac-council.org)      [info@eac-council.org](mailto: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,  
Gandhinagar, Gandhinagar, Gujarat-382010  
Email: [info@stainchly.com](mailto:info@stainchly.com)  
Phone: +91 792 402 3887  
Company Registered in England with Company Number 11488663




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

FDA Bhawan, Kotha 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.sanoji@gmail.com](mailto: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 his own laboratory or in any other laboratory registered under sub-rule (3) of rule 31.

## CLEFT LIP & PALATE INSTRUMENTS

Cleft Palate Raspatory - French Pattern  
Right & Left in Pair



Category No.
1142.01

Cleft Palate Raspatory - Barsky Type

Right & Left in Pair



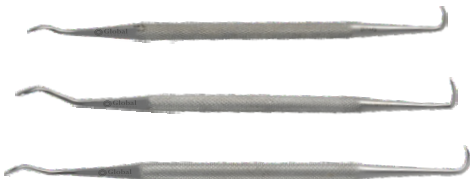
Category No.
1142.02

Double Ended



Category No.
1142.02

McIndoe Cleft Palate Raspatory



Category No.	Size
1142.06	Small
1142.07	Medium
1142.08	Big

Cleft Palate Raspatory - Curved



Category No.	Size
1142.04	Up
1142.05	Down

Barsky Pharyngeal Flap Elevator



Category No.
1143

Mitchell Trimmer



Category No.
1144

Cleft Palate Knife - Triangular



Category No.  
1145

Cleft Palate Hook

Right Angle



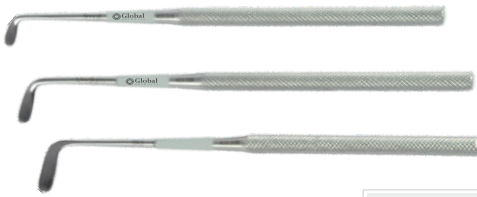
Category No.  
1146.01

Down Bent



Category No.  
1146.02

Cronin Cleft Palate Elevator



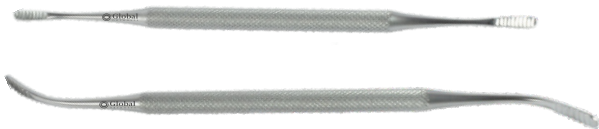
Category No.	Size
1147.01	Small - Right
1147.02	Small - Left
1147.03	Med - Right
1147.04	Med - Left
1147.05	Big - Right
1147.06	Big - Left

Palate Dissector  
Right & Left in Pair



Category No.  
1148

Miller Bone File



Category No.	Size
1150.01	Straight
1150.02	Curved

Spoon Shape Elevator - Double Ended



Category No.  
1149



Elevator Double Ended



Category No.	Size
1151.01	Right & Left
1151.02	Side & Flat





### **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](mailto:inquiry@globalorthosys.com), [globalorthosys18@gmail.com](mailto: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](http://www.globalorthosys.com)