

CE 1434



Simple Cutting Edge **Safety**
 Contemporary **Quality** Crafted Precision
 Implantology



“Synergy of Excellence”

Best-in-Class Products



- Kamal Engineering group founded in 1973, is one of the industry leaders in the design and manufacture of specialty equipments for the Hydrocarbon Industry. The expertise in manufacturing complex products as per customers' specifications has led to a high acceptability of their products – the world over.



Our Philosophy

- World Class Quality
- Cutting Edge Research and Technology
- Compliance with International Regulatory Norms
- Environment Friendly Processes



- Scientific Waste Disposal



We believe in

- Transparency
- Professional Ethics
- Safe and healthy work environment



- Commitment to Green Operations and Environment



- Kamal Medtech is an Environment Friendly Company



- CSR activities as a good Corporate Citizen

Research Partners



Indian Institute of Technology Delhi

iFix Dental Implant has been Conceptualized, Designed & Developed by Indian Institute of Technology (IIT), Delhi in collaboration with Maulana Azad Institute of Dental Sciences (MAIDS), Delhi



Maulana Azad Institute of Dental Sciences
New Delhi

iFix Dental Implant has been Clinically studied at Maulana Azad Institute of Dental Sciences, New Delhi



Council of Scientific and Industrial Research

Under the Patronage of Council of Scientific & Industrial Research (CSIR) - NMITLI Program



Manufacturers of high quality medical devices of global standards

MILESTONES

Establishment of manufacturing facilities (KAMAL MEDTECH)

2018

2019

License obtained for manufacturing & commercialization

The best in-class technology was transferred to market pioneers (KAMAL MEDTECH)

2016

2017

US Patent grant (US patent # 9833300)

Filing for US patent

2009

2016

First test license obtained (IIT)

MAIDS and IIT joined hands with CSIR to do best in class product developments

2007

2008 to 2011

Complete development & research
•Design / drawing developments (IIT & MAIDS)
•Manufacturing at pilot scale (IIT & MAIDS)
•Pre-clinical & clinical studies (IIT & MAIDS)

Initiation of project by Council of Scientific & Industrial Research (CSIR)

2007

2007

Introduction of team IIT (Indian Institute of technology)

2005 to 2006

Conceptualization of design by 'Maulana Azad Institute of Dental Sciences' (MAIDS) team



Certificate No. MD-QMS/91/R/2609

This is to certify that

Kamal Encon Industries Ltd.

Plot No. 917, Sector 68, IMT Faridabad – 121 001, Haryana, India

has been found to conform to the requirements of
Medical Devices - Quality Management System Standard

ISO 13485:2016

This certificate is valid for the following scope :

Design, Development, Manufacture and Sales of :

- (1) **Interventional Cardiology Products :**
 - Sirolimus Eluting Coronary Stent System
 - Everolimus Eluting Coronary Stent System
- (2) **Dental Implants and Prosthesis**

Manufacture and Sales of Surgical Kits

Initial Certification : 27/07/2019
Valid until : 26/07/2022



The authenticity of this document may be re-affirmed by writing to certification@zenithworldwide.com. Lack of fulfillment of conditions as set out in the Certification Agreement may render this certificate invalid. Any alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of law.
Accreditation Body: National Accreditation Board for Certification Bodies (NABCB)
Quality Council of India (QCI), 2nd Floor, Institution of Engineers Building, Bahadur Shah Zafar Marg,
New Delhi – 110 002, India
www.nabcb.qci.org.in
Issuing Authority: Zenith Quality Assessors Pvt. Ltd.
306, 4th Floor, Sai Apex, Vinnagar, Pune - 411014,
Maharashtra, India
www.zenith-worldwide.com
CNABCBMDQMS16-SS00022019 (D.8.2)



FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/MD/2019/000057

1. M/s KAMAL ENCON INDUSTRIES LIMITED, 56 INDUSTRIAL ESTATEYAMUNA NAGAR, --, Haryana (India) - 135001 Telephone No.: 1123351365 FAX: 1123721657 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s KAMAL ENCON INDUSTRIES LIMITED, Plot No. 917, IMT Faridabad, Sector- 68, Faridabad, Haryana (India) - 121001 Telephone No.: 11-23723158, 11-23351369 FAX: 11-23721657
2. Details of medical device(s) [Annexed]
3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer
4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	<p>Generic Name:Dental Implants with Abutments & Prosthesis Model No.:NIL Intended Use:Dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. Class of medical device:Class C Material of construction:Titanium Alloy, Ti-6Al-4V Dimension(if any):Diameter (mm): 3.00, 3.50, 4.00, 4.50, 5.00 & 5.50 AND Length (mm): 7.50, 8.50, 10.00, 11.50, 13.00 & 15.00 Shelflife:60 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):IFix, MultiFix, SFix, CFix</p>

Place:

Date29-May-19

Central Licensing Authority



सत्यमेव जयते

प्रधान मंत्री
Prime Minister

MESSAGE

It is heart-warming to learn that an indigenous technology for dental implants has been developed by Council of Scientific and Industrial Research in collaboration with IIT-Delhi and Maulana Azad Institute of Dental Sciences.

We remain firm in our resolve to provide the latest and best treatment as well as make it affordable for the poor and the disadvantaged sections of the society. The indigenously developed technology would surely help make cost effective treatment available to all. The emphasis must also be on 'Zero Defect and Zero Effect' while designing and manufacturing products.

The painstaking efforts made by the doctors, scientists and technical experts to develop technology for dental implants will boost the morale of the scientific and technical fraternity.

I congratulate the all involved in the development of the technology and hope that they will continue to work with increased vigour, commitment and dedication in the service of the nation.

May the technology make a lasting contribution in securing health and well-being of the common people of our country.

(Narendra Modi)

New Delhi

कार्तिक 15, शक संवत् 1941

6th November, 2019

Dr. Harsh Vardhan

Union Minister of Science & Technology,
Earth Sciences and Health & Family Welfare
209, Anusandhan Bhawan
2, Rafi Marg
New Delhi - 110001



World class facility for Cardiac stents & Dental implants

Kamal Medtech has commissioned 50,000 Sq. ft state of the art manufacturing facility at IMT Faridabad, Haryana. the facility has been built as per International Standard ISO 13485. Kamal Medtech is a leading enterprise specialized in Research, Design, Development, Manufacturing & Supply of High End Medical Devices.

- Ultramodern manufacturing facility
- Manufacturing facility and quality management system compliant with fifth schedule of MDR 2017 & ISO 13485 Standard
- State-of-the-art clean rooms
- High-tech quality control laboratories
- Sophisticated production equipments
- Best in class technologies resulting into superior product quality



“i-Fix represents the ultimate solution in dental implantology for maximum functionality in all bone types.”

- We aim at Integrated extensive R&D, design, processing, manufacturing and a stringent quality management system to create high quality implants.
- The vision of Kamal Medtech is to manufacture niche precision engineered products with global quality standards and i-Fix implant system is the first step in this direction.



Advanced Machine & Material

- Most advanced state of the art CNC machines (Swiss Tornos)
- Foremost manufacturing technologies ensuring maximum precision
- Using high quality titanium alloys Grade 23 (Grade V ELI)

Clean Room & Packaging

- Best in-class clean room manufacturing & packaging facilities
- Advanced cleaning processes at par with global standards
- As per ISO: 13485 standard
- Specialized packaging ensuring long term sterility

Cutting Edge

PRODUCT QUALITY

“The confidence of beautiful teeth
...for a lifetime”

Surface Technology for Better Osseointegration

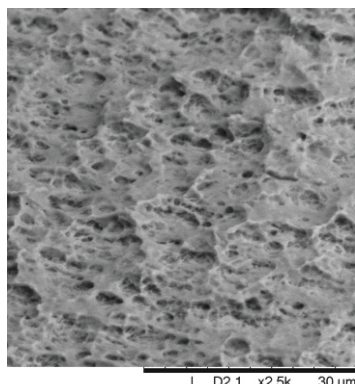
- Macro roughness for accelerated osseointegration
- State of the art surface treatment technology: Increase early bone to implant contact
- Increased secondary stability
- Clinical research data of iFix Implant has shown excellent osseointegration studied by MicroCT and Histo-morphometry
- Shortened healing period

Macro roughness
on the buttress
threads

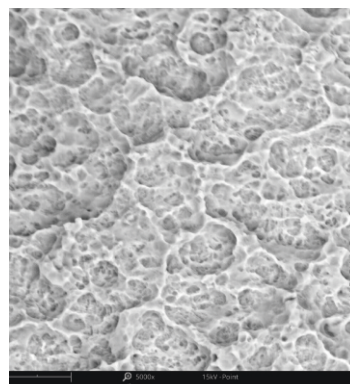


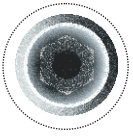
SEM of i-Fix Implant Surface

Magnification 2500



Magnification 5000

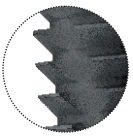




Connection

For simplified assembly and confidence for component positioning.

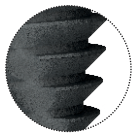
- The implant system has the advantage of having one prosthetic platform for all diameters
- The implant abutment connection is an internal hex design which provides a rigid connection and stable biological seal
- Emerging bevel conical connection.
- Precise fit and meticulous tolerances
- Platform switching incorporated in all connections in order to move the abutment-implant interface away from the bone-implant interface
- 12° Morse taper creates an optimal seal against bacterial endotoxin leakage, while maintaining excellent retention



Optimized Thread

Variable thread design from coronal to apical part allows gradual bone condensation

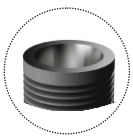
- Buttress thread engineered for superior primary stability
- The Coronal back Taper for Enhanced soft and Hard tissue integration.
- Reduction of stresses in bone at both crestal and cancellous level



Anatomical Tapered Design

For maximum bone volume around implant for improved soft tissue support

- Allows self-tapping properties
- Provides excellent primary stability
- Flat tip for better engagement
- Minimal instrumentation- all implants can be placed using the same kit



Surface

For accelerated and improved osseointegration process

- Clinically proven Sand blasted, large grit, acid etched (SLA) surface
- Macro roughness for predictable osseointegration
- SLA has proven clinical efficacy in early implant loading

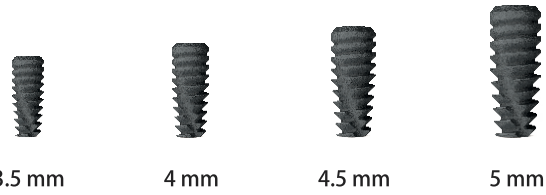
World class
dental restoration
solutions

Cutting edge
designs backed by
proven technology
and clinical evidence

Affordable
and Simple

Size Table

Diameter (mm)	Length (mm)						
	6.5	7.5	8.5	10	11.5	13	15
3.5	✗	✗	✓	✓	✓	✓	✓
4	✓	✓	✓	✓	✓	✓	✓
4.5	✓	✓	✓	✓	✓	✓	✓
5	✓	✓	✓	✓	✓	✓	✗



Clinically tested & Proven



i-Fix Dental Implants have been Clinically tested and proven to have excellent osseointegration.

Overview of Pre-Clinical Studies

A. Biocompatibility Studies:

A series of biocompatibility tests as per ISO 10993 series have been conducted. The biocompatibility testing included the tests for Cytotoxicity, Sensitization, Irritation, Acute systemic toxicity, Sub-acute & sub-chronic toxicity, Genotoxicity and Implantation. In all of these tests, the implants were non-reactive and produced no greater response than the negative control employed in each test system.

B. Animal Study:

In vivo animal study was conducted to evaluate safety, efficacy and overall product performance. Animal studies used Rabbit model for specimen implantation for 6 weeks and 12 weeks. The result demonstrated that no tissue necrosis or local infection were evident and the implant showed excellent osseointegration.

S. No.	SPECIMEN/ WEEKS	PERCENT BONE FORMATION
1	12 weeks	80.5 %
2	6 weeks	25.6 %

C. Clinical Study:

i-Fix Implants have been comprehensively evaluated in an extensive clinical trial at M.A.I.D.S, New Delhi and have demonstrated excellent results.

“Smart Surgical Kit”



Designed to fit all Prosthetic tools and drills.

Compact and easy to carry.

Easy cleaning and autoclavable.

“Everything should be made
as simple as possible but
not simpler” - Albert Einstein

Made in India for the World.



EN ISO 13485:2016 Certified Company

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Empowered by Innovation