

SUSHRUT®-ADLER®

1ST Indian Orthopedic Group to bring you a complete product range licenced by Indian Drug Regulatory Authority

You now have absolute confirmation of having made the right choice!

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FORM 20
(For Rule 56)

License to manufacture for sale for distribution of drugs specified in Schedule C and C (1) [excluding those specified in Schedule A].

Number of license and date of issue: NO-469, Dt-20/05/2008

1. M/S Adler Mediequip Pvt Ltd

It is hereby licensed to manufacture at the premises situated at the Plot No. 25, HSIIDP, PO-Hahy, Taluka-Sangameshwar, Dist-Ratnagiri, Pin-415804 Maharashtra

the following drugs, being drugs specified in Schedules C and C (1) [excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1954:

Names of Drugs as per List Attached

2. Names of approved expert staff for Mfg. Mr. Milind More, For Testing - Mr. Shrikrishna Joshi

3. The license is subject to the way of withdrawal during and after the issue of the license as per the Rules for the drug manufacturers under the license subject to the conditions (with no limitation for sale)

4. The license shall be in force from 20/05/2008 to 29/05/2010

5. The license is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the Drugs and Cosmetics Act, 1954.

Signature: H. D. Saha
Designation: Joint Secretary

Date of issue: 20/05/2008

6. This license and all the conditions attached thereto shall be kept on the approved premises and shall be produced on the request of the Drug and Cosmetics Act, 1954.

7. If the license holder is not satisfied with the conditions of the license for manufacture of any drug specified in Schedule C and C (1) [excluding those specified in Schedule X] and included above, he should apply to the Licensing Authority for modification of the license as provided in rule 71 (1). The license will be deemed to be renewed if no application is received to the Licensing Authority.

8. Any change in the particulars of the license shall be reported to the Licensing Authority.

9. The licensee shall inform the Licensing Authority in writing in the event of any change in the total address of the manufacturing unit for the license. When any change in the constitution of the firm takes place

1. Copy of the Drugs Manufacturing Licence dated 30th May 2008 issued by the FDA/CLAA
2. Copy of the approved product range annexed to the Licence issued by the FDA/CLAA

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List of Products for license in Form no. 20 under license No.: NO-469 dt: 20/05/2008

M/S. Adler Mediequip Pvt. Ltd.,
At: Munadpur, PO. Hahy, Tal. Sangameshwar,
Dist. Ratnagiri, Maharashtra State, PIN 415804, India

S.No.	Brand Name	Product Name
	Adler	Bone Screws
	Adler	Bone Plates
	Adler	Pins and Wires
	Adler	Hern Endoprosthesis
	Adler	Joint Replacement Prosthesis
	Adler	Custom Built Implants
	Sushrut	Other Implants
	Sushrut	Bone Screws
	Sushrut	Bone Plates
	Sushrut	Pins and Wires
	Sushrut	3M Nails
	Sushrut	Hern Endoprosthesis
	Sushrut	Other Implants
	Adler	Pins and Wires
	Adler	Screws
	Adler	3M Nails
	Adler	Spine Implants
	Adler	Bone Screws
	Adler	Bone Plates
	Adler	Spine Implants
	Adler	Spine Implants
	Adler	Bone Plates
	Adler	Bone Screws
	Adler	3M Nails
	Adler	Joint Replacement Prosthesis
	Adler	Bone Screws
	Adler	Bone Plates
	Adler	Spine Implants
	Adler	Spine Implants
	Adler	Hern Endoprosthesis
	Adler	Joint Replacement Prosthesis
	Adler	Joint Replacement Prosthesis
	Adler	3M Nails

Signature: [Signature]
Manager

ATLER MEDIEQUIP PVT. LTD.
At: Munadpur, Post-Hahy,
Tal: Sangameshwar
Dist: Ratnagiri, Pin-415804
Tel: 023341240179
Fax: 023341240336



Regulatory Update on Orthopaedic Implants

Earlier, towards the end of 2006 and early 2007, we had updated you on the fact that the Government of India had introduced regulation of various medical devices including orthopaedic implants, by designating them as 'Drugs'.

It is now a matter of the greatest pride and pleasure for the Sushrut Adler Group to report to you that Adler Mediequip Pvt. Ltd., the manufacturing company of the Sushrut-Adler Group, is the FIRST Indian Orthopaedic Manufacturing Company to be awarded with the Drug Manufacturing License.

As our valued customers who have trusted us for many years, you now have absolute confirmation of having made the right choice.

The FAQ below has been prepared in the interest of general awareness of all stakeholders, manufacturers, dealers and distributors, hospitals and user surgeons as there are legal compliance requirements related to regulated products.

When were orthopaedic implants brought under regulatory control?

On 7th October 2005, the Government of India brought 10 categories of medical devices, including orthopaedic implants, under regulatory control, through gazette notification number G.S.R. 627(E).

What is a Drug Manufacturing Licence or a Drug Import License?

A Drug Manufacturing Licence (or a Drug Import License) is a document approved for issue by the CLAA (Central License Issuing Authority). The Drug Manufacturing License is issued by the State FDA (Food and Drug Administration) office under approval of the CLAA and is endorsed by the Drug Controller of India who is the designated CLAA for all Medical Devices including orthopaedic implants.

This license is issued to manufacturers (for manufactured products) or importers (for imported products) who have applied for the respective licence and complied with all requirements of the regulatory process defined under the law. It is important to note that a Drug Manufacturing Licence (for manufacture of products) or a Drug Import Licence (for Import of products) is a license that specifically pertains to individual products and is not a general quality system certificate.

What is the significance of the list of products that should accompany a manufacturing license in Form-28?

It is the list of products that clearly shows which are the products that have been granted the manufacturing license by the regulatory authorities. It is important to note that both the Form-28 as well as the annexed list of products are to be countersigned by the Drug Controller General of India, in order to be considered as valid and legal.

Is there some marking or labeling on the products that shows that the product is licenced by the Drug Authorities?

The Manufacturing License carries with it a manufacturing license number. As per the law, it is mandatory for the manufacturing license number to be printed on the product label. For example, all products from the Sushrut-Adler Group will be carrying our manufacturing license number KD-469.

What is a Drug Selling License?

A Drug Selling License is a license granted to a retailer / agent / dealer / distributor authorizing him to sell products that have a valid manufacturing license.

What is the difference between the Drug Manufacturing License and the Drug Selling License?

A Drug Manufacturing License is applicable to a manufacturer.

A Drug Selling License is applicable to a seller/agent/retailer/dealer/distributor.

The Manufacturing License is issued by the Central Regulatory Authority in a form known as Form-28 and consists of two parts. First is the Form-28 which is the actual manufacturing license. The second part is the list of actual products that the manufacturing license is applicable for.

The Selling License is issued by respective State FDA offices to sellers/retailers/agents/dealers/distributors in two forms known as Form-20B and Form 21-B.

What does this regulation mean for dealers and distributors of these products?

For dealers and distributors of orthopaedic implants, it is legal and safe to distribute and sell Sushrut-Adler products as long as they have the drugs 'selling licence'.

What does this mean for Hospitals and Orthopaedic Surgeon users of our products?

For our surgeon users, this is not only confirmation that it is safe and legal to use our products but is also a re-confirmation of the faith and trust they have had in our products and quality for many years.

What does this mean for products that are being sold (or used) today without a valid manufacturing or import licence?

Medical Devices designated as "Drugs", which include orthopaedic implants, that do not meet legal regulatory requirements applicable as on date are no longer safe to manufacture, sell or use from a legal standpoint.

Are both Sushrut and Adler products covered in our licence application?

One of the major pro-active steps we took in early 2006 was to formalize the Sushrut manufacturing alliance with Adler. In the re-structuring operation that was carried out, Adler acquired all manufacturing assets of Sushrut.

By virtue of this alliance, Sushrut (and all Sushrut products) has gained from the years of International manufacturing experience and expertise possessed by Adler as well as the benefit of the Adler CE and ISO certifications.

Adler Mediequip is thus the manufacturing company which manufactures all products for the group (including the SUSHRUT and ADLER brands as well as the other Adler brands like Zeta, Titan, UMEX, Eazee etc.) and Sushrut Surgicals Pvt. Ltd. is re-structured exclusively as the marketing company for the group.

Thus, all our manufactured products (Sushrut, Adler and all other brands) are covered under the regulatory control as part of our Adler Drug Manufacturing Licence.

Sushrut Surgicals being the exclusive marketing company has already been issued with a "selling licence" to sell all products.

What is the status of unlicensed products being sold in the market?

As is clear from the provisions of the Drugs and Cosmetics Act, it is not legally allowed for a manufacturer to make supplies to a dealer or distributor who does not possess a valid selling licence; just as how it is not legally allowed for a dealer to purchase products from a manufacturer who does not meet the requirements given in the notification & clarification guidelines or from an importer who does not have a valid drug import licence.

What actions will be taken against those who are producing, selling, distributing or using non-licensed illegal products?

While no actions are evident as yet, we have seen a number of cases where local FDA offices in various states have made enquiries with our business partners about the status of licensing for the products they sell or distribute.

What we must remember is that any activity of sales, usage or distribution of products not meeting legal requirements as on date is an act of breaking the law of the land and agencies of the Government reserve the right to take punitive actions.

While it is difficult to predict the exact nature of the actions, it is likely that these actions would gradually increase as the enforcement machinery of the Government (Office of the Drug Controller, State FDA offices etc.) gears up to tackle this relatively new activity.

In the meantime, it is clear that any person, as of today, who is engaging in sales, distribution, stocking or usage of products that do not meet the legal requirements is taking all the risks that are associated with breaking the law*.



ADLER™ MEDIEQUIP PVT. LTD.



SUSHRUT SURGICALS PVT. LTD.

Sushrut House, Survey No. 288, Next to MIDC Hinjewadi Phase II, At Maan,
Tal. Mulshi, Pune 411 057, India. Tel: +91(0)20 66520700 Fax: +91(0)20 66520800
e-mail: info@sushrut.com Internet: www.sushrut.com