



# Management System Certificate

Certificate No. **MD-QMS/91/R/1718**

This is to certify that

**Sharma Pharmaceutical Pvt. Ltd.**

at

**444, GIDC Estate, Waghodia – 391 760,  
Vadodra, Gujarat, India,**

meets the registration requirements for Management System Standard :

**ISO 13485:2016**

This certificate is valid for the following products / services :

**Design, Development, Manufacture, Supply and Export of  
Orthopaedic Implants, Instruments and related Medical Accessories.**

Initial Certification : 11<sup>th</sup> October, 2010  
Current Approval : 20<sup>th</sup> July, 2016  
Valid until : 19<sup>th</sup> July, 2019



Authorised Signatory

This Certificate is valid when confirmed by data listed in the International Register of Quality Assessed Organisations <[www.iso.org](http://www.iso.org)>. Further clarification regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained by consulting the certified organization. Lack of fulfillment of conditions as set out in the Certification Agreement may render this certificate invalid.

**Zenith Quality Assessors Pvt. Ltd.**

306, 4th Floor, 1st Apex, Near Datta Mandir, Vasan Nagar, Pune - 411 014, Maharashtra, India.  
[www.zenith-worldwide.com](http://www.zenith-worldwide.com)

**Accreditation Body : ACCREDITATION SERVICE FOR CERTIFYING BODIES (EUROPE) Ltd.**  
**6, Ferris Place, Bournemouth, Dorset, BH8 6AU, United Kingdom.**  
**[www.ascb.co.uk](http://www.ascb.co.uk)**

# FORM 26

(See Rules 73 and 83)

## Certificate of Renewal of licence to manufacture for sale of Drugs Other than those specified in Schedule X

Certified that Licence in Form 28 No: G/28/1302 Granted on the Date: 04/05/2009

To M/s. SHARMA PHARMACEUTICAL PVT.LTD

for the manufacture of the drugs Specified in Schedule C and C(1) excluding those specified in Schedule "X" to the Drugs and Cosmetics Rules, 1945, at the premises situated at,

444, G.L.D.C. ESTATE, WAGHODIA, DIST - VADODARA - 391 760

has been renewed from : 04/05/2014 To 03/05/2019

Name(s) of drugs (each item to be separately specified) : As per list Approved & Annexed.

Names of approved competent technical staff : As per list Approved & Annexed.



Signature :

Designation :

Commissioner  
Food & Drugs Control Administration  
Gujarat State.

Date:- 24/03/2015

Central Licence Renewal Authority

Central Drugs Standard Control Organisation (HQ)  
Government of India  
Ministry of Health and Family Welfare  
PDA Bhawan, Noida Road, New Delhi-110002



# Certificate of Compliance



Confirms that the Class 1 complies according to the directive 93/42/EEC Medical Council Directive

**Certificate No.: CE-3365**

## Manufacturer

**Name : SHARMA PHARMACEUTICAL PRIVATE LIMITED**

**Address : 444, GIDC Estate, Waghodia-391760, Vadodara, Gujarat, India**

**Products : Orthopaedic Instruments (As attached Annexure-I to III)**

## Complies with the requirements applicable to it

The manufacturer's technical documentation as required for Medical Council according to the directive 93/42/EEC has been reviewed and found to comply with the requirements for Class I Medical Devices Directive. Any significant changes in the design or construction of the product, not agreed upon by us, this declaration will lose its validity.

## This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are not changed.
3. The certificate validity is conditioned by positive results of surveillance audits.
4. 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 with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

**Validity of this certificate can be verified at [www.ukcertifications.co.uk/verify](http://www.ukcertifications.co.uk/verify)**

**Date of Certification 15<sup>th</sup> March 2018**

**1<sup>st</sup> Surveillance Audit Due 14<sup>th</sup> March 2019**

**2<sup>nd</sup> Surveillance Audit Due 14<sup>th</sup> March 2020**

**Certificate Expiry (subject to the company maintaining its system to the required standard) 14<sup>th</sup> March 2021**

*Daniel..*

**Authorised Signatory**







Certificate No. QMS/91/R/1718/a

This is to certify that

## Sharma Pharmaceutical Pvt. Ltd.

Regd. Office & Works : 444, GIDC Estate, Waghodia - 391 760,  
Vadodara, Gujarat, India

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

## ISO 9001:2015

This certificate is valid for the following scope :

**Design, Development, Manufacture, Sales and Export of :**

- **Non-Active, Non Sterile Orthopaedic Implants - Trauma, Maxillofacial, Arthroscopy, Spinal, Joint and Prosthesis**
- **Non-Active, Non Sterile Orthopaedic Surgical Instruments and Orthopaedic External Fixation System**

Initial Certification : 19/12/2009

Re-certification : 24/08/2018

Valid until : 18/12/2021

(Replaces withdrawn Certificate No. QMS/91/R/1718 issued on 18<sup>th</sup> October, 2015)



**UK**

Authorised Signatory

This Certificate is valid when confirmed by data listed in the International Register of Quality Assessed Organisations <[www.irqao.org](http://www.irqao.org)>.

The authenticity of this document may be re-affirmed by writing to [certification@zenith-worldwide.com](mailto:certification@zenith-worldwide.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: Accreditation Service for Certifying Bodies (Europe) Ltd.**  
6, Ferris Place, Bournemouth, Dorset, BH8 0AU, United Kingdom.  
[www.ascb.co.uk](http://www.ascb.co.uk)

**Issuing Authority: Zenith Quality Assessors Pvt. Ltd. - MSCD001**  
306, 4th Floor, Sai Apex, Vimanagar, Pune-411014, Maharashtra, India  
[www.zenith-worldwide.com](http://www.zenith-worldwide.com)