

Certificate of Registration

This is to certify that

ADVIN HEALTH CARE

424-MARUTI PLAZA, SARDAR PATEL CHOWK ROAD, KRISHNANAGAR, AHMEDBAD-382345, GUJARAT, INDIA.

has been assessed and certified by RSMS certification as meeting the requirements of

ISO 13485: 2015

For the following activities

MANUFACTURER AND SUPPLIER OF MEDICAL EQUIPMENTS
INSTRUMENTS, IMPLANTS AND SURGICAL DISPOSABLES FOR UROLOGY
LAPAROSCOPY, GYNECOLOGY, NEPHROLOGY, ORTHOPEDIC
GASTROLOGY, CARDIOLOGY, ENT, OPHTHALMIC, DENTAL
PHYSIOTHERAPY AND LABORATORY DEPARTMENTS FOR HOSPITAL.

Date of Registration: 17 May 2019 1st Surveillance Due: 16 May 2020 2nd Surveillance Due : 16 May 2021 Recertification Due : 16 May 2022

Certificate No:- MDQMS-1967551

To Verify this Certificate Please Visit at www.rsmscert.com







P-5/1, Street No-1, Jassian Road, Surinder Parl Haibowal, Ludhiana, Punjab, 141001

info@rsmscert.com www.rsmscert.com

This Certificate is Valid for 3 years Subject to annual Surveillance audit to be done Successesfully (AN ISO CERTIFICATION BODY)

Authenticity of the Certificate can be verified at www.uk-eu-acc.org.uk



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WHO GMP

For the following activities

MANUFACTURER AND SUPPLIER OF MEDICAL EQUIPMENTS INSTRUMENTS. IMPLANTS AND SURGICAL DISPOSABLES FOR UROLOGY LAPAROSCOPY, GYNECOLOGY, NEPHROLOGY, ORTHOPEDIC GASTROLOGY, CARDIOLOGY, ENT, OPHTHALMIC, DENTAL PHYSIOTHERAPY AND LABORATORY DEPARTMENTS FOR HOSPITAL.

Date of Registration: 17 May 2019 1st Surveillance Due: 16 May 2020 2nd Surveillance Due: 16 May 2021 Recertification Due: 16 May 2022

Certificate No:- GMP/196125

To Verify this Certificate Please Visit at www.rsmscert.com





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Certificate of Compliance

We hereby declare that the technical file of product complied with the requirement of directives Medical Device Directive 2007/47/EC

Certificate no. CE-AVHC-20-132465

Manufacture

Name Address : ADVIN HEALTH CARE

: 424, MARUTI PLAZA, SARDAR PATEL CHOWK ROAD,

KRISHNANAGAR, SAIJPUR BOGHA, AHMEDABAD - 382345,

GUJARAT, INDIA

Product

MEDICAL EQUIPMENT, INSTRUMENTS, IMPLANTS AND SURGICAL DISPOSABLES FOR UROLOGY LAPAROSCOPY, GYNECOLOGY, NEPHROLOGY, ORTHOPEDIC GASTROLOGY, CARDIOLOGY, ENT, OPHTHALMIC, DENTAL PHYSIOTHERAPY AND LABORATORY DEPARTMENTS FOR HOSPITAL

Complies with the requirements applicable to it

The Certification body has performed an audit of the above product quality system covering the 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 directives Medical Device Directive 2007/47/EC

This certificate is issued under the following conditions:

- 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.
- The certificate remains valid until the manufacturing conditions or the quality systems are changed.
- The certificate validity is conditioned by positive results or surveillance audits.
- 4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.
- 5. 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.gaafs.us

Date of Certification 1st Surveillance Due 2nd Surveillance Due

04TH March 2020 03RD March 2021 03RD March 2022

Certificate Expiry (Subject to the company maintaining its system

03RD March 2023

To the required standard)



Authorized Signatory



Validity of this Certificate is subject to Annual Surveillance audits done successfully

This certificate remains the property of QCAS and must be returned whenever demanded CCAS is an independent system product and personal assessment body QCAS is accredited by

Global Accreditation Assessment Forum Series (GAAFS)