No: S-GMP & QMS/22093530/ /B

Commissioner

56630

Food & Drugs Control Administration, Gujarat State, Dr. Jivraj Mehta Bhavan, Block No.8, 1st floor, Gandhinagar

Date:

\_ 7 SEP 2022

To,
M/s. SHREE BHAGWATI SURGICAL,
7 UMIYA NAGAR,
MEAR C'TM CROSS ROAD,
AMRAIWADI, AHMEDABAD - 380 026

Sub: Drugs & Cosmetics Act, 1940 & Rules there under. Issue of S-GMP & QMS/ Certificate

Sir.

Ref:- Your letter Dated: 03/09/2022

I send herewith Quality Management System (QMS) in ONE copy as desired by you.

Yours faithfully,

for Commissioner

Food & Drugs Control Administration

No: S-GMP & QMS/22093530/2022/ /

/B Gandhinagar Date:

Copy forwarded to :-

- 1. Assistant Commissioner, AHMEDABAD 380 026
- 2. G-Branch.

for Commissioner Food & Drugs Control Administration



## Food & Drugs Control Administration BLOCK NO. 8, 15 FLOOR, Dr. JIVRAJ MEHTABHAVAN. GANDHINAGAR, GUJARAT STATE INDIA PIN: 382010



Certificate No.: S-GMP & QMS/22093530

## Quality Management System Certificate (Q.M.S.) for Medical Devices

This is to certify that M/s. SHRTT BHAGWATI SURGICAL, 7 UMIYA NAGAR, NEAR CTM CROSS ROAD, AMRAIWADI, Dist. - AHMEDABAD - 380 026. is holding valid Medical Devices Manufacturing License in form MD - 5 bearing No. MFG/MD/2020/000206 issued by this administration under the provision of Drug and cosmetic Act, 1940 & Rules & Medical Devices Rules 2017 under the saul licence the firm is permitted to manufacture & sale Drugs Covered under the following categories.

Dosage Form (s)	Category (ies)
Sterile Disposable Infusion Set with & whitout Air Vent, Sterile Disposable M. V. Set with & whitout Air Vent, Sterile Disposable Blood Administration Set with & whitout Air Vent & Other Non Sterile Medical Devices	

The said firm is observing Good Manufacturing Practices and as stipulated in the 5" Schedule of Quality Management System for Medical Devices as per the provision of Drug and Cosmetic Act, 1940 and Medical Devices Rules, 2017. This firm is having its own in house Testing Laboratory.

This certificate shall not be anyway provide immunity from Penal Provisions so far as matter arising out of provisions of the Drug and Cosmetic Act, 1940 and Medical Devices Rules, 2017 and likely to be withdrawn / cancelled at any time during validity period if it found that the firm is not observing mandatory requirements.

The manufacturing plant is subjected to inspection at suitable intervals by competent authority. This certificate is valid from Dt : 07/09/2022 to 06/09/2024

Commissioner

Food & Drugs Control Administration Gandhinagar, Gujarai State

(Dr. H. G. XOSHIA)

Email

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Phone-

: 91-79-23253417, Fax: 91-79-232-53400