

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Device & Diagnostic Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Phone No-011-23236965
Fax: 23236973

File No. : HQ/MD/2023/001249

Dated : 09-OCT-2023

To,
M/s SPM Medicare Pvt Ltd,
B-40, Phase 2, Noida
Noida, Gautam Buddha Nagar, Uttar
Pradesh (India) - 201305
Telephone No.: 9711008401 FAX: 120
4634949 Email:
UMANG@SPMMEDICARE.COM

**Sub:- Test Licence in Form MD-13 to manufacture the medical devices under Medical Device Rules, 2017-
regarding.**

Sir,

Test Licence No. MFG/TL/MD/2023/000660 is hereby forwarded to you. This licence is subject to following conditions

1. The licensee shall use the medical device manufactured under licence granted under sub-rule (3) of rule 31 exclusively for the purpose of testing at the place specified in the licence;
2. The licensee shall allow any Medical Device Officer to enter, with or without notice, the premises where the medical device are manufactured and to satisfy himself that only Testing is being conducted on such device;
3. The licensee shall maintain a record of the quantity of medical device manufactured, tested and stocked and its disposition.
4. The components shall comply with quality standards and shall be procured from certified sites. Further the final product shall comply with MDR-2017, if the manufacturing licence is to be obtained, based on the data generated through this test licence.

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Yours faithfully

RAJEEV SINGH
RAGHUVANSHI
HI

Digitally signed by RAJEEV SINGH
RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION, ou=RAJEEV SINGH
RAGHUVANSHI
2.5.4.20=80c6216a23e4eafbe8a239774cdeb03
c2769041015a06564fe67f54b765db1cb,
postalCode=600034, st=TAMIL NADU,
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02D0E1FE73CFA12A1A126EA94FA5701124A1
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FORM MD-13

[See sub-rule (3) of rule 31]

Licence to Manufacture Medical Devices for the purpose of Testing

Licence No. : MFG/TL/MD/2023/000660

1. M/s SPM Medicare Pvt Ltd, B-40, Phase 2,Noida Noida, Gautam Buddha Nagar, Uttar Pradesh (India) - 201305 Telephone No.: 9711008401 FAX: 120 4634949 Email: UMANG@SPMMEDICARE.COM is hereby licenced to manufacture the medical device(s) specified below for the purpose of Testing at M/s SPM Medicare Pvt. Ltd., B-40, Phase II, Gautam Buddh Nagar, Noida, Uttar Pradesh, 201305 , Gautam Buddha Nagar, Uttar Pradesh (India) - 201305 Telephone No.: 9711008401 FAX: 0120-8407070718.

S.No	Medical Device Details
1	1. Generic Name :Soft Tissue Trephine (Disposable Circumcision Stapler) 2. Class of Medical Device :Class B 3. Quantity Permitted to be manufactured :1000 Nos.

2. The licence is subject to the provision of the Medical Devices Rules , 2017 and conditions prescribed therein.
3. The licence shall be in force for a period of three year from the date specified below.


Place: New Delhi

Date: 09-OCT-2023

RAJEEV
SINGH
RAGHUVANSHI

Central Licensing Authority

Digitally signed by RAJEEV SINGH RAGHUVANSHI
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, o=RAJEEV SINGH RAGHUVANSHI,
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postalCode=600034, st=TAMIL NADU,
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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO
MINISTRY OF HEALTH, GOVERNMENT OF INDIA
सत्यमेव जयते