

# 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. : AZ/MD/2024/000012**

**Dated : 26-NOV-2024**

To,

**M/s ORTHOFLEX MEDISYS INDIA PVT LTD,  
REG OFFICE 2ND FLOOR SHIV MARKET OPP BUS  
STATION VISNAGAR  
VISNAGAR, --, Gujarat (India) - 384315  
Telephone No.: 09727973005 FAX: 02765225295 Email:  
rakemax@yahoo.com**

**Sub:- Loan Licence to manufacture for Sale or for Distribution of Class C or Class D  
medical device in Form MD-10 under Medical Device Rules, 2017- regarding.**

Sir,

Loan licence No. **MFG/MD/2024/000816** in Form MD-10 is hereby forwarded to you. This licence is subject to following conditions

1. Licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority.
2. The licence holder shall inform the Central Licensing Authority of the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder;
3. The licence holder shall obtain prior approval from the Central Licensing Authority, before any major change as specified in the Sixth Schedule is carried out and the Central Licensing Authority shall indicate its approval or rejection within forty five days and in case where no communication is received within the stipulated time from such Authority, such change shall be deemed to have been approved;
4. The licence holder shall inform any minor change as specified in the Sixth Schedule to the Central Licensing Authority within a period of thirty days after such minor change take place;
5. The licence holder shall carry out test of each batch of product manufactured prior to its release for compliance with specifications either in his own laboratory or in any other laboratory registered under sub-rule (3) of rule 83;





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## FORM MD-10

[See sub-rule (1) rule 25]

### Loan Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Loan Licence Number: **MFG/MD/2024/000816**

- M/s ORTHOFLEX MEDISYS INDIA PVT LTD, REG OFFICE 2ND FLOOR SHIV MARKET OPP BUS STATION VISNAGARVISNAGAR, --, Gujarat (India) - 384315 Telephone No.: 09727973005 FAX: 02765225295** has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at **M/s ELECTRO MAGNETIC INDUSTRIES, BLOCK NO.686, AWAKHAL - SADHLI ROAD, AT & PO- AWAKHAL, TAL.- SINOR,, Vadodara, Gujarat (India) - 391250 Telephone No.: 0265-6541361 FAX: 0265-6541361**
- Details of medical device(s) [Annexed]
- The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): **As per records maintain by the manufacturer**
- This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

### ANNEXURE

S.No.	Details Of Device(s)
1	<b>Generic Name:</b> Gamma sterilization of Class C Medical Devices <b>Model No.:</b> NIL <b>Intended Use:</b> Not Applicable <b>Class of medical device:</b> Class C <b>Material of construction:</b> NA <b>Dimension(if any):</b> <b>Shelflife:</b> NIL <b>Sterile or Non sterile:</b> Sterilized <b>Brand Name(if registered under the Trade Marks Act, 1999):</b> NIL
2	<b>Generic Name:</b> Gamma sterilization of Class D Medical Devices <b>Model No.:</b> NIL <b>Intended Use:</b> Not Applicable <b>Class of medical device:</b> Class D <b>Material of construction:</b> NA <b>Dimension(if any):</b> <b>Shelflife:</b> NIL <b>Sterile or Non sterile:</b> Sterilized <b>Brand Name(if registered under the Trade Marks Act, 1999):</b> NIL

Place:

Date:26-Nov-24

**RAJEEV SINGH**  
**RAGHUVANSHI**  
Central Licensing Authority

Digitally signed by RAJEEV SINGH RAGHUVANSHI  
DN: cn=RAJEEV SINGH RAGHUVANSHI, o=CENTRAL DRUGS STANDARD CONTROL ORGANISATION, ou=CENTRAL DRUGS STANDARD CONTROL ORGANISATION, 2.5.4.20=42d7189b1c0981bb5a263a4a73d025f4b11b680a91f08779480f00a42ee361b, postalCode=110002, st=Delhi, serialNumber=6575e47d9409858f03bdc902d0e1fe73cfa12a1a26ea94f5701124a19013, cn=RAJEEV SINGH RAGHUVANSHI