The Use of very Lower Power Remote Cardiac Monitoring Radio Frequency Wireless Medical Devices, Medical Implant Communication System (MICS) Or Medical Implant Telemetry Systems (MITS), and other such very Low Power Medical Radio Frequency Wireless Devices or Equipments (Exemption from Licensing Requirement) Rules, 2008

UNION OF INDIA India

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Rule THE-USE-OF-VERY-LOWER-POWER-REMOTE-CARDIAC-MONITORING of 2008

- Published on 23 September 2008
- Commenced on 23 September 2008
- [This is the version of this document from 23 September 2008.]
- [Note: The original publication document is not available and this content could not be verified.]

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1738.

G.S.R. 673 (E), dated 23rd September, 2008. - In exercise of the powers conferred by Sections 4 and 7 of the Indian Telegraph Act, 1885 (13 of 1885) and Sections 4 and 10 the Indian Wireless Telegraph Act, 1933 (17 of 1933), the Central Government hereby makes the following rules, namely :-

1. Short title and commencement.

(1)These rules may be called the Use of Very Lower Power Remote Cardiac Monitoring Radio Frequency Wireless Medical Devices, Medical Implant Communication System (MICS) or Medical Implant Telemetry Systems (MITS), and other such Very Low Power Medical Radio Frequency Wireless Devices or Equipments (Exemption from Licensing Requirement) Rules, 2008.(2)These rules shall be applicable in the 402-405 MHz frequency band.(3)They shall come into force on the date of their publication in the Official Gazette.

2. Definition.

- In these rules, unless the context otherwise requires,---(a)"Act" means the Indian Telegraph Act, 1885 (13 of 1885);(b)"Effective Radiated Power" includes the gain of the antenna, if any;(c)Words and expressions used in these rules and not defined but defined in the Act and the Indian Wireless Telegraphy Act, 1933 (17 of 1933), shall have the same meanings respectively as assigned to them in those Acts.
- 3. Use of Very Low Power Remote Cardiac Monitoring Radio Frequency Wireless Medical Devices, Medical Implant Communication System (MICS) or Medical Implant elementary Systems (MITS) and other such very Low Power Medical Radio Frequency Wireless Devices or Equipments in the 402-405 MHz frequency band.
- Notwithstanding anything contained in any law for the time being in force, no licence shall be required by any person to establish, maintain, work, possess or deal in any wireless equipment for the purpose of usage of very low power remote cardiac monitoring radio frequency wireless medical devices, Medical Implant Communication Systems (MICS) or Medical Implant Telemetry Systems (MITE), and other such very low power medical radio frequency wireless devices or equipments in the 402-405 MHz frequency band, on non-interference, non-protection and shared (non-exclusive) basis, with the Maximum Effective Isotropic Radiated Power and other technical parameters as specified in the Table below, namely:-TABLEFrequency Band Maximum Effective Radiated Power Type of Antenna(ERP) and Emission Bandwidth

1 2 3 402-405MHz Maximum Effective Radiated Power (Maximum (ERP) of 25 microWatt Built-in or less, with channel emission bandwidth within 300 KHz.

Antenna

4. Interference.

- The effect of unwanted energy due to one or a combination of emissions, radiations, of induction upon reception in a radio communication system, manifested by any performance degradation, misinterpretation, or loss of information which could be extracted in the absence of such unwanted energy, where any person whom a licence has been issued under Section 4 of the Act, informs that his licensed system is getting harmful interference from any other radio communication system exempted under these rules, the user of such unlicensed wireless equipment shall take necessary steps to avoid interference by relocating the equipment, reducing the power using special type of antenna including discontinuation of such wireless use, if required :Provided that, before such discontinuation, a reasonable opportunity to explain the circumstances shall be offered to such unlicensed user of wireless equipment.

5. Equipment.

(1)The medical wireless device or equipment shall be type approved and designed and constructed in such a manner that the bandwidth of emission and other parameters shall conform to the limits specified in the Table referred to in above rules.(2)The application for obtaining equipment type approval shall be made to the Central Government in such application format which shall be available on website; www.wpc.dot.gov.in.

6. Conditions.

- These rules,-(i)do not in any way, affects the licensing rights or procedures of existing and planned wireless operation, in this frequency band; (ii) are not applicable, wherever specific service license is required from the Central Government.