



ABSTRACT

Drugs Control Administration – Medical Devices Rules, 2017 – Delegation of certain power vested with Director of Drugs Control to Assistant Director of Drugs Control under the Medical Devices Rules, 2017.

HEALTH AND FAMILY WELFARE (M1) DEPARTMENT

G.O (Ms) No.20

Dated:17.01.2018

திருவள்ளூர்வராண்டு 2049

ஹேவிளம்பி, தை - 04

Read :

1. Medical Devices Rules, 2017 published in the Gazette of India, Extraordinary New Delhi, dated 31.01.2017 vide Notification No.G.S.R 78(E).
2. From the Director of Drugs Control, Chennai, Letter No.20340/E1/2017, dated 19.12.2017.

ORDER:

In the reference first cited, the Central Government has enacted and notified separate rules namely "*Medical Devices Rules 2017*" under the Drugs and Cosmetics Act 1940 in exercise of its legislative powers conferred by Section 12 and Section 33 of the said Act 1940 vide notification number G.S.R.78(E), dated 31.01.2017 in addition to the existing Drugs and Cosmetics Rules, 1945 in matters relating to the regulation of certain notified Devices, in-vitro Diagnostics and other substances which are covered by the definition of Drugs by Section 3 (b) of the said Act 1940 (herein after referred to as Medical Devices).

2. This Medical Devices Rules 2017, which came into force with effect from 01.01.2018 intends to regulate and exercise control over the certain Medical Devices which are covered by the definition of Drugs by Section 3 (b) of the said Act 1940.

3. As per rule 9(3) of Medical Devices Rules 2017, the Director of Dugs Control is empowered to delegate any of its powers under the Medical Devices Rules, 2017 to any officer under its control by an order in writing with approval of the State Government.

4. The Director of Drugs Control has now requested the Government to permit him to delegate the powers which were exercised by him under the

Medical Devices Rules, 2017 as State Licensing Authority to the Zonal Assistant Director of Drugs Control, relating to the issue of licenses of sales establishments of notified medical devices, diagnostics and other substances which are covered by definition of Drugs under Section 3 (b) of the said Act 1940 in exercise of power conferred by Rule 9 (3) of the Medical Devices Rules, 2017.

5. The Government after careful examination have decided to accept the request of the Director of Drugs Control and permit the Director of Drugs Control to delegate the powers which were exercised by him under Medical Devices Rules, 2017 as State Licensing Authority to the Zonal Assistant Director of Drugs Control, relating to the issue of licenses of sales establishments of notified medical devices, diagnostics and other substances which are covered by definition of Drug under Section 3 (b) of the said Act 1940 in exercise of power conferred by Rule 9 (3) of Medical Devices Rules, 2017.

(BY ORDER OF THE GOVERNOR)

**J. RADHAKRISHNAN
PRINCIPAL SECRETARY TO GOVERNMENT**

To

The Director of Drugs Control, Chennai – 6.

All the Zonal Assistant Director of Drugs Control,
(through the Director of Drugs Control, Chennai)

The Accountant General, Chennai – 18.

The Pay and Accounts Officer (South), Chennai – 35.

Copy to:

The Special Personal Assistant to Hon'ble Minister for
Health and Family Welfare, Chennai-9.

The Health and Family Welfare (Data Cell) Department, Chennai – 9.
Stock File / Spare Copy.

// FORWARDED / BY ORDER //

Phis
24.1.18
SECTION OFFICER
22/1/18