NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** India  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:** Department of Pharmaceuticals  **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**  Shri Sandeep Kumar  Under Secretary to the Government of India  Department of Pharmaceuticals  Ministry of Chemicals and Fertilizers  Room N0. 302, B wing, Janpath Bhawan  New Delhi – 110011, India  Tel: +91-11-23319517  Email: [sandeep.k68@nic.in](mailto:sandeep.k68@nic.in)  Website: <http://www.pharmaceuticals.gov.in> |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****X],** **5.7.1 [****],** **other:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Infant Radiant Warmer, Multifunction Patient Monitoring Equipment, Pulse Oximeter Equipment |
| **5.** | **Title, number of pages and language(s) of the notified document:** Medical Devices - Medical Electrical Equipment (Quality Control) Order, 2018 (2 page(s), in English) |
| **6.** | **Description of content:** Medical Devices - Medical Electrical Equipment (Quality Control) Order, 2018 |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:**  (i) Health safety of Consumers  (ii) Higher level of quality, reliability and consistency  (iii) Protection of environment |
| **8.** | **Relevant documents:** To be published in the Gazette of India (available in English and Hindi) |
| **9.** | **Proposed date of adoption:** Yet to be decided  **Proposed date of entry into force:** Come into force with effect from the date of its publication in the official Gazette |
| **10.** | **Final date for comments:** 60 days from notification |
| **11.** | **Texts available from: National enquiry point [** **]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  Shri Sandeep Kumar  Under Secretary to the Government of India  Department of Pharmaceuticals  Ministry of Chemicals and Fertilizers  Room N0. 302, B wing, Janpath Bhawan  New Delhi – 110011, India  Tel: +91-11-23319517  Email: [sandeep.k68@nic.in](mailto:sandeep.k68@nic.in)  Website: <http://www.pharmaceuticals.gov.in> |