

No: W-47/38/2021-IPHW
Government of India
Ministry of Electronics and Information technology
IPHW Division

Electronics Niketan
6 CGO Complex, Lodhi Road
New Delhi-110003
Dated : 01.09.2021

Clarification

Subject: Clarification regarding coverage of camera used in medical devices- reg

The Government of India, Ministry of Electronics and Information Technology (MeitY), has mandated Compulsory Registration for product categories notified under the schedule of the "Electronics and IT Goods (Requirement of Compulsory Registration) Order, 2012 (CRO)". The "Digital Camera" and "Video Camera" are notified under the schedule of CRO for compliance to IS 13252m (part-1) :2010 and IS 616:2017 respectively.

2. In this regard, it is clarified that the camera(s) used in medical equipment having registration as per provision of Medical Device Amendment Rules, 2020 notified vide G.S.R. 102 (E) dated 11.02.2020 by Ministry of Health & Family Welfare and tested & certified with IEC 60601, are exempted from provision of CRO.

3. This issues with the approval of Competent Authority.

(Saurabh Ranjan)
Scientist 'D'
Tel: 011-24301764
email: saurabh.r@gov.in