

File No. DCGI/Misc/2020(119)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(DCGI Secretariat)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 22.05.2020

ADVISORY NOTICE


Subject: Voluntary registration of Personal Protection Equipment (PPE) Coveralls at CDSCO and its testing at Labs recognised by Ministry of Textiles – Regarding.

Personal Protection Equipment (PPE) Coveralls is an important medical device for the healthcare professionals, handling Covid-19 patients and situations. Earlier, PPE Coveralls were not being manufactured in India. Looking at this National need in Covid-19 situation, with the support of Ministry of Textiles, a large number of domestic manufacturers have now started producing PPE coveralls. However, the coveralls are being procured by nominated agency of Ministry of Health only after these pass the prescribed test at the labs recognised by Ministry of Textiles.

2. It is pertinent to mention that, Ministry of Health and Family Welfare has, vide SO 648(E) dated 11.02.2020 notified the definition of Medical Devices under the Drugs and Cosmetics Act under Section 3 b (iv), along with its regulations including the voluntary registration scheme for such items (including PPE Coveralls) under Medical Device Rules, issued vide GSR 102(E) dated 11.02.2020

3. In light of the above, it is important that all the manufacturers of this medical device (PPE coverall) are aware of the latest rules governing Medical Devices, enabling them to also take advantage of the provisions of voluntary registration with CDSCO.

4. Accordingly, the PPE Coveralls manufacturers may also consider getting themselves registered voluntarily on the CDSCO Medical Device online portal i.e. cdscomdonline.gov.in to secure a registration number from CDSCO, which will also be a benchmark for their quality management system.


(Dr. V. G. Somani)
Drugs Controller General (India)

To

1. All Stakeholders including Preventive Wear Manufacturers Association of India
2. All State/UT Drug Controllers - for information and necessary action.
3. All Zonal/Sub Zonal offices of CDSCO – for information and necessary action.

Copy to:

1. PS to JS (R), Ministry of Health & Family Welfare, Nirman Bhavan, New Delhi.

ANNEXURE

Testing facilities of the Labs recognised by Ministry of Textiles

- i. South India Textile Research Association, Coimbatore, Tamil Nadu
- ii. Defence Research 86 Development Establishment, Gwalior now at INMAS (DRDO) laboratory at Delhi.
- iii. Heavy Vehicles Factory, Avadi, Tamil Nadu
- iv. Small Arms Factory, Kanpur, Uttar Pradesh
- v. Ordnance Factory at Muradnagar, Uttar Pradesh
- vi. Ordnance Factory at Kanpur, Uttar Pradesh
- vii. Ordnance Factory Ambernath (Near Mumbai), Maharashtra
- viii. Metal and Steel Factory, Ishapore (Near Kolkata), West Bengal