No. 31026/36/2016-MD
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
*****

Janpath Bhawan, New Delhi
Dated, the 16 October, 2018

OFFICE MEMORANDUM

Subject: Guidelines for implementing the provisions of Public Procurement (Preference to Make in India) Order (PPO), 2017, related to procurement of Goods & Services in Medical Devices – reg.

This issue of mandatory requirement of USFDA/CE certification in public procurement has been raised from time to time by Medical Device Industry representatives. This Department has considered the issue and hereby amends the guidelines dated 18.5.2018 issued by this Department for implementation of PPO 2017 dated 15.06.2017 issued by Department of Industrial Policy & Promotion, by inserting Para 4.1 as under:

2. "4.1. Every procurement agency should follow the standards laid down by Bureau of Indian Standards, for the medical device concerned, for procurement purposes. Where such standards exist, USFDA/CE certifications etc. shall not be mandated."

3. Other contents of the guidelines dated 18.05.2018 remain unchanged.

16/10/18

(Parveen Kumar)
Under Secretary to the Government of India
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To

As per list attached.

Copy to: DG, Bureau of Indian Standards

Director (NPC)/DoP – For uploading on the website