

Acceptance of eIFU for medical device a welcome move: MTal

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Notification in line with regulatory practices of several advanced countries



Medical Technology Association of India, which represents leading research-based medical technology companies with significant investments in India has welcomed the Ministry of Health & Family Welfare Gazette notification on acceptance of eIFU (electronic Instructions for Use) for Medical Device and Equipment and said that the regulation is line with governments push for digitalization to reduce the use of Paper.

Ministry of Health & Family Welfare on January 15, 2019 published Gazette notification on acceptance of eIFU for Medical Device and Equipment. "The acceptance of eIFU for Medical Device and Equipment puts India's regulatory specifications in line with the practices of some of the advanced countries like Singapore, USA and countries of Europe and will improve users access to more detailed and up-to-date information," said Mr. Pavan Choudary, Chairman and Director General, MTal.

MTal further said that the inclusive approach of CDSCO and Health Ministry in considering suggestions encourages the industry. "Many products cannot be supplied with Paper IFU as the product is transferred to the loaner kit in the supply chain and sterilized before being supplied to the doctor, the acceptance of eIFU will remove such issues." Mr. Pavan Choudary added. MTal had made several representations to the CDSCO for the acceptance of eIFU for Medical Device and Equipment.

About Medical Technology Association of India (MTal)

Medical Technology Association of India (MTal – pronounced as Em-tai) is a not-for-profit organization duly registered under sub-section (2) of section 7 of the Companies Act, 2013 and Rule 8 of the Companies (Incorporation) Rules, 2014.

MTal is an association of research-based medical technology companies who have made remarkable investments in Manufacturing, R&D and Health Care Workers Training in India. MTal represents a wide spectrum of the medical device industry with global experience in innovation and manufacturing. All the time stressing on the three hallmarks of healthcare - Quality, Consistency and Patient Safety, MTal wants to be a responsible voice of the industry. The association is committed to improving access to affordable and quality healthcare for patients.

MTal looks to partner with the Government of India in setting a roadmap for the growth of medical devices sector by bringing

in even bigger investments in this sector, through 'Make in India' and through technology upgradation and dissemination in the provider space.