

Government Facilitates faster imports of key medical devices by relaxing the conditions for clearances under Legal Metrology (Packaging Rules 2011)

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Considering the present pandemic situation of COVID-19 and for meeting the demand of medical devices, Department of Consumer Affairs, Government of India has permitted the importers of medical devices to import the following categories medical devices for three months from 28.04.2021 onwards, subject to the condition that the importers shall make all declarations required under these rules immediately after import/custom clearance and before sale by way of stamping or putting sticker or online printing, as the case may be:

- (i) Nebulizers,
- (ii) Oxygen concentrators,
- (iii) Continuous positive airway pressure (CPAP) devices,
- (iv) Bilevel positive airway pressure (BIPAP) devices]
- (v) Oxygen concentrator along with flow meter, regulator, connectors and tubing
- (vi) Vacuum Pressure Swing Absorption (VPSA) and Pressure Swing Absorption (PSA) oxygen plants, Cryogenic Oxygen Air Separation Units (ASUs) producing liquid/ gaseous oxygen
- (vii) Oxygen Cannister
- (viii) Oxygen Filling Systems
- (ix) Oxygen cylinders including cryogenic cylinders
- (x) Oxygen Generators
- (xi) Parts to be used for the manufacture of equipment for production, transportation, distribution or storage of Oxygen
- (xii) Any other device from which Oxygen can be generated
- (xiii) Ventilators (capable of functioning as high-flow devices) with nasal canula; Compressors including all accessories and tubing; humidifiers and Viral filters
- (xiv) High flow nasal canula device with all attachments
- (xv) Helmets for use with non-invasive ventilation
- (xvi) Non-invasive ventilation oronasal masks for ICU ventilators
- (xvii) Non-invasive ventilation nasal masks for ICU ventilators

Department of Consumer Affairs, administers the Legal Metrology Act 2009. The act provides for application of legal requirements to measurements and measuring instruments. The objective of Legal Metrology is to ensure public guarantee from the point of view of security and accuracy of the weightings and

measurements. The Legal Metrology (Packaged Commodities), Rules 2011 are primarily intended to ensure that the consumers are able to make informed choices by being informed of essential declarations on the pre-packed commodities.

The advisory is issued to cater the steep demand for the medical devices mentioned above by enabling the speedy clearance of these goods amid the second wave of Covid in the country. The Government of India has allowed this flexibility for labelling the essential medical devices post custom clearance but before sale for making the expeditious clearance of these life saving devices. The importers, importing the medical devices under this permission shall inform all such imports with quantity imported to the Director (Legal Metrology) and the Controller (Legal Metrology) in the State, where the import is made, immediately after import.

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