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### PART I : SECTION (I) — GENERAL

#### **Government Notifications**

L.D.B 9/2016 (II).

#### THE NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 OF 2015

REGULATIONS made by the Minister of Health and Indigenous Medical Services under Section 142 of the National Medicines Regulatory Authority Act, No. 5 of 2015 read with Section 3(i) of aforesaid Act.

PAVITHRA WANNIARACHCHI (M.P.) (ATTORNEY-AT-LAW), Minister of Health, and Indigenous Medical Services.

Colombo, 20th March, 2020.

#### Regulations

- 1. These Regulations may be cited as the Medical Devices (Availability within Sri Lanka) Regulations, No. 2 of 2020.
- 2. A person shall not export or re-export from Sri Lanka any Medical device specified in the Schedule hrereto without prior written approval of the National Medicines Regulatory Authority.



#### **SCHEDULE**

(Regulation 2).

#### MEDICAL DEVICES

No.	Approved Name of the Medical Devices
1.	Disposable Surgical Face Mask - Three ply layers - Non Woven (Earloop or Tie on Type)
2.	Face Mask - N 95 type - (Surgicial/ Healthcare / Respiratory / Medical)