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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.

PAVITHRA WANNIARACHCHI (M.P.),
(Attorney-at-Law),
Minister of Health, and Indigenous Medical Services.

Colombo, 16th of March, 2020.

#### Regulations

The Pricing of Medical Devices Regulations, No. 1 of 2020 published in the *Gazette* Extraordinary No. 2160/28 of January 29, 2020 are hereby amended as follows:-



- (1) by the insertion of following new regulation immediately after regulation 8 thereof
  - **"8 A.** A person shall not export or re-export from Sri Lanka any medical device specified in Column I of the Schedule hereto without prior written approval of the National Medicines Regulatory Authority."
- (2) by repeal of Schedule thereof, and the substitution therefor of the following:-

#### **SCHEDULE**

(Regulation 2)

#### MAXIMUM RETAIL PRICES OF SELECTED MEDICAL DEVICES

No.	Column I	Column II
	Approved Name of the Medical devices	Maximum Retail Price (MRP) per unit (SLR)
1.	Disposable Surgical Face Mask - Three ply layers — Non woven (Earloop or Tie on type)	50.00
2.	Face Mask - N 95 type – (Surgical / Healthcare / Respiratory / Medical)	325.00