



29 APR 2020

FDA CIRCULAR
No. 2020-009-B

SUBJECT: AMENDMENT TO INCLUDE RESPIRATORY THERAPY DEVICES IN THE LIST OF MEDICAL DEVICES COVERED BY FDA CIRCULAR NO. 2020-009, AS AMENDED BY FDA CIRCULAR NO. 2020-009-A

The listing of health products enumerated under Section IV- Scope of FDA Circular No. 2020-009, as amended by FDA Circular No. 2020-009-A, entitled "Guidelines on the Identification, Notification, Evaluation, Regulatory Enforcement Action, and Review and Monitoring of Donated Health Products Solely Intended to Address COVID-19 Public Health Emergency is hereby amended to include "Respiratory Therapy Devices."

Therefore, the listing provided under said Section of the subject Circular shall be amended to read as follows:

1. Face Masks including N-95 Masks,
2. Shoe Covers,
3. Gloves,
4. Head Covers,
5. Gowns,
6. Goggles/ Face Shields,
7. COVID-19 Diagnostic Test Kits,
8. Alcohol, Hand Sanitizers, etc.
9. Ventilators, Respirators, their respective Accessories, and **Respiratory Therapy Devices**
10. Other health products that may hereinafter identified and listed by the FDA.

This issuance shall take effect immediately.

For your information and guidance.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

