



27 MAR 2020

FDA CIRCULAR
No. 2020-009-A

SUBJECT: AMENDMENT TO INCLUDE VENTILATORS, RESPIRATORS AND THEIR RESPECTIVE ACCESSORIES TO THE LIST OF MEDICAL DEVICES COVERED BY FDA CIRCULAR NO. 2020-009

The listing of health products enumerated under Section IV- Scope of FDA Circular No. 2020-009, or *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 ventilators, respirators and their respective accessories.

Hence, 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 and their respective Accessories, and**
10. Other health products that may hereinafter be identified and listed by the FDA.

This Order shall take effect immediately.

For your information and guidance.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

