Republic of the Philippines
Department of Health
Food And Drug Administration
Civic Drive, Filinvest City, Alabang, Muntinlupa City

CERTIFICATE OF MEDICAL DEVICE NOTIFICATION

Pursuant to provisions of Republic Act No. 3720 as amended, known as the Foods, Drugs, Devices and Cosmetics Act and Republic Act 9711, known as the Food and Drug Administration (FDA) Act of 2009 and it's implementing Rules and Regulations (IRR), the product described hereunder has been found to conform with the requirements and standards for marketing authorization of medical device products per existing regulations in force as of date hereof.

CMDN NO:	**CDRRHR-CMDN-2020-667287**
Product Name:	**3M Aura™ Health Care Particulate Respirator and Surgical Mask**
Classification:	Class A
Shelf-Life:	5 years
Commercial Presentation:	20 pieces per box
Intended Use:	Intended to help reduce wearer exposure to certain airborne particles, including those generated by electrocautery, laser surgery, and other powered medical instruments. As a surgical mask, it is designed to be fluid resistant to splash and spatter of blood and other infectious materials.

This authorization shall be valid until **14 August 2025** , subject to the conditions listed on the next page. No change in the information, labelling and commercial presentation of this product shall be made at any time during the effectivity of this registration without prior written approval of this Office.

This authorization is subject to suspension, cancellation or recall should any violation of R.A. 3720 and R.A. 9711 and/or regulations issued thereunder involving the product be committed.

Witness My Hand and Seal of this Office, this **14 August 2020**

BY AUTHORITY OF THE DIRECTOR GENERAL

MARIA CECILIA C. MATHENZO
Officer-in-Charge
Center for Device Regulation, Radiation Health, and Research

Verify at http://www.fda.gov.ph/verification/cmdn/verified.php?id=CDRRHR-CMDN-2020-667287

MANDATORY REQUIREMENTS:

1. This product must be available only in drugstores, hospitals and other legal outlets. The labelling of each device must be stated:
   a. The date (month/year) within which to use said device, whenever applicable.
   b. The lot of batch number, whenever applicable.
   c. Product registration number.
   d. Name and address of importer/local distributor.

SPECIAL CONDITION:

Provided that nothing in the registration of the product herein granted shall be interpreted or construed as an endorsement or representation by FDA and that the registrant has the right privilege to the use of the name or brand so registered. The Registrant hereby agrees and affirms to indemnify and/or hold FDA free and harmless against any and all third-party claims on infringement of patent, trademark or industrial design rights arising from the registration of the product(s) listed on the first page.

CMDN Number: **CDRRHR-CMDN-2020-667287**
Product Name: **3M Aura™ Health Care Particulate Respirator and Surgical Mask**

Principal Name:	3M Health Care
Address:	St Paul, Minnesota, United States of America
Legal Manufacturer Name:	3M Health Care
Address:	St Paul, Minnesota, United States of America
Physical Manufacturer Name:	3M Health Care
Address:	St Paul, Minnesota, United States of America
Trader Name:	Not Applicable
Address:	Not Applicable
Distributor / Importer Name:	3M Philippines, Inc.
Address:	10th and 11th Floors, The Finance Centre, 26th corner 9th avenue, Bonifacio Global City, Taguig. 1634
Distributor / Wholesaler Name:	3M Philippines, Inc.
Address:	10th and 11th Floors, The Finance Centre, 26th corner 9th avenue, Bonifacio Global City, Taguig. 1634

Codes/Sizes/Reference Numbers and Colors:

1870+