



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 its 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-2020-643322**

Product Name: **EMS N88 Surgical Face Mask**

Classification: Class A

Shelf-Life: 2 years

Commercial Presentation: 50 units/box

Intended Use: Intended to be worn by personnel during medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material transfer.

This authorization shall be valid until **23 June 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 **23 June 2020**

BY AUTHORITY OF THE DIRECTOR GENERAL


MARIA CECILIA C. MATENZO
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-2020-643322>

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-2020-643322

Product Name: EMS N88 Surgical Face Mask

Principal Name: Not Applicable

Address: Not Applicable

Legal Manufacturer Name: EMS Components Assembly, Inc.

Address: 117 Technology Avenue, Laguna Technopark, Inc. SEPZ, Brgy. Malamig, Biñan, Laguna

Physical Manufacturer Name: Not Applicable

Address: Not Applicable

Trader Name: Not Applicable

Address: Not Applicable

Distributor / Importer Name: Not Applicable

Address: Not Applicable

Distributor / Wholesaler Name: N/A

Address: N/A

Codes/Sizes/Reference Numbers and Colors:

Size: Length 175 mm; Width 95 mm

Item Code: EM 100-101

Color: Blue