



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-2023-1112535**

Product Name: **NovaPACS (Picture Archiving and Communication Systems)**

Classification: Class B (CMDN)

Shelf-Life: n/a

Commercial Presentation: Downloadable System

Intended Use: NovaPACS is intended for the viewing, archiving, analysis, annotation, registration, distribution, editing, fusion, and processing of digital medical images and data acquired from diagnostic imaging devices and all DICOM devices, including mammography.

This authorization shall be valid until **01 November 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 **01 November 2023**

BY AUTHORITY OF THE DIRECTOR GENERAL


MARIA CECILIA C. MATIENZO
Directory IV

Center for Device Regulation Radiation Health and Research



Verify at

https://verification.fda.gov.ph/Medical_Device_CMDNview.php?showdetail%3D%26APP_UID%3D814711106643dcff44

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-2023-1112535

Product Name: NovaPACS (Picture Archiving and Communication Systems)

Principal Name: Novarad Corporation
3152 North University Ave.,
Suite 200
Address: Provo, UT 84604
USA

Legal Manufacturer Name: Novarad Corporation
3152 North University Ave.,
Suite 200
Address: Provo, UT 84604
USA

Physical Manufacturer Name: Novarad Corporation
3152 North University Ave.,
Suite 200
Address: Provo, UT 84604
USA

Trader Name: Not Applicable
Address: Not Applicable

Distributor / Importer Name: Enterprise Imaging Technologies Inc
Unit 1208 12/F Centuria Medical Makati, Kalayaan Ave., corner Salamanca St., Makati City, Metro Manila
Address: Philippines

Distributor / Wholesaler Name: Enterprise Imaging Technologies Inc.
Unit 1208 12/F Centuria Medical Makati, Kalayaan Ave., corner Salamanca St., Makati City, Metro Manila
Address: Philippines

Codes/Sizes/Reference Numbers and Colors:

Version 8.9.3

