



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



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-2023-1244306**
Product Name: **PICA Whole Body MRI System**
Classification: **Class B (CMDN)**
Shelf-Life: **N/A Service Life: 10 years**
Commercial Presentation: **1 unit per box**
Intended Use: **Intended for Used for magnetic resonance imaging system for medical diagnosis through scan and visualize images in any directions**

This authorization shall be valid until **25 February 2026**, 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 **25 February 2024**

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%3D41119024665af3194

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-2023-1244306
Product Name:	PICA Whole Body MRI System
Principal Name:	Time Medical Limited
Address:	Flat/Rm 301 3/F 20E, 20 Science Park East Avenue, Hong Kong Science Park, NT, Hong Kong
Legal Manufacturer Name:	Time Medical Limited
Address:	G/F Bio-Informatics Centre No.2 Science Park West Avenue Hong Kong Science Park Shatin, New Territories Hong Kong
Physical Manufacturer Name:	Time Medical Limited
Address:	G/F Bio-Informatics Centre No.2 Science Park West Avenue Hong Kong Science Park Shatin, New Territories Hong Kong
Trader Name:	Not Applicable
Address:	Not Applicable
Distributor / Importer Name:	Time Medical Philippines Inc.
Address:	Unit 107, Eastwood ICITE Building, Eastwood City Cyberpark, 188 E. Rodriguez Jr. Avenue, Bagumbayan, Quezon City, Metro Manila
Distributor / Wholesaler Name:	Time Medical Philippines Inc.
Address:	Unit 107, Eastwood ICITE Building, Eastwood City Cyberpark, 188 E. Rodriguez Jr. Avenue, Bagumbayan, Quezon City, Metro Manila

Codes/Sizes/Reference Numbers and Colors:

Model number: TMS-MRI-3500WB-02
list of Accessories PICA MRI System
QC phantom 23.03.00032V
Positioning cushion & mattress 18.01.01020S
Operation manual & disc 18.06.99001M
Patient physiological gating module 17.14.01008V
Intercom system 17.11.01001P

