GE Healthcare

EU DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745.

We

Manufacturer	EU Authorized Representative
GE Medical Systems LLC 3000 North Grandview Blvd Waukesha, WI 53188, USA	GE Medical Systems SCS 283 rue de la Minière 78530 BUC, France
Single Registration Number (SRN): US-MF-000018315	FR-AR-000000344

Manufacturing Site

GE Medical Systems Israel, Functional Imaging

4 Hayozma Street,TIRAT HACARMEL, 30200,
Israel

Single Registration Number (SRN):

IL-MF-000003062

Declare under our sole responsibility that the device:

Omni Legend

Basic UDI: 8406821BUG00208H6

Identification number: Product Configuration Master (PCM) PCM-PET0012.

Intended Purpose:

The Omni Legend PET/CT system is intended for CT attenuation corrected, anatomically localized PET imaging of the distribution of positron-emitting radiopharmaceuticals. It is intended to image the whole body, head, heart, brain, lung, breast, bone, the gastrointestinal and lymphatic systems, and other organs. The system is also intended for stand-alone, diagnostic CT imaging

EMDN (CND) Codes and Description: Z110203- Integrated Systems for CT/PET

GMDN Code: 40644 Nuclear Medicine System, Positron Emission Tomography

37618 X-ray System, Diagnostic, Computed Tomography, Full-body

Class: IIb

Classification rule (Annex VIII): Rule 10 & 11

To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that apply to it. Omni Legend is in compliance with EU Directive 2011/65/EU and EU Directive 2015/863/EU. This conformity is based on the following elements:

- Technical Documentation reference: DOC2606384, of the product to which this declaration relates.
- EC certificate Nº 38720
- Conformity assessment procedure followed: Annex IX
- Delivered by GMED, Notified Body number: 0459

Date: 22-October-2024

This EC Declaration of Conformity supersedes the previous declaration dated 07-May-2024.