

EU DECLARATION OF CONFORMITY

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

We:

Manufacturer	EU Authorized Representative
GE Medical Systems SCS 283, rue de la Miniere 78530 Buc, France Single Registration Number (SRN): FR-MF-000000687	N/A

Manufacturing Site
GE Medical Systems SCS 283, rue de la Miniere 78530 Buc, France

Declare under our sole responsibility that the device:

AW Server (version: 3.2)

Basic UDI-DI: 8406821BUG00119H6

Identification number: 5719780

LOT number: AWS03D02E6D4

Intended Purpose: AW Server is a medical software system that allows multiple users to remotely access AW applications from compatible computers on a network. The system allows networking, selection, processing and filming of multimodality DICOM images.

Both the client and server software are only for use with off the shelf hardware technology that meets defined minimum specifications.

The device is not intended for diagnosis of mammography images. The device is not intended for diagnosis of lossy compressed images. For other images, trained physicians may use the images as a basis for diagnosis upon ensuring that monitor quality, ambient light conditions and image compression ratios are consistent with clinical application.

EMDN Code: Z11069092

EMDN Description: VARIOUS DIGITAL BIOIMAGING MANAGEMENT INSTRUMENTS - MEDICAL DEVICE SOFTWARE

GMDN Code: 41670

GMDN Description: Picture Archiving and Communication System, Software

Risk Class: IIa

Classification rule (in Annex VIII): Rule 10 and Rule 11

To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that apply to it.

This conformity is based on the following elements:

- Technical Documentation reference: DOC2478160, of the product to which this declaration relates.
- EU certificate N° 38329:
 - Conformity assessment procedure followed: Annex IX Chapter I and III (Quality management system) with sampling of technical documentation assessment as specified in section 4 of Annex IX
 - Delivered by GMED (Notified Body 0459)
- List of common specifications applied and in relation to which conformity is declared: Not Applicable
- List of harmonized standards applied in relation to which conformity is declared:
EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 14971:2019+A11:2021, EN 80001-1:2011
EN 62304:2006+A1:2015, EN 82304-1:2017, EN 62366-1:2015+A1:2020

Signature:			
Name:			Function: Senior Regulatory Affairs Manager
Date of Issue:	10-JAN-2025	Place of Issue:	Buc, France

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