



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:

Allia IGS 3

Allia IGS 5

Basic UDI-DI: 8406821BUG00099HR

Identification number: 5874604, 5872892

Intended Purpose: The angiographic X-ray systems are indicated for use for patients from newborn to geriatric in generating fluoroscopic and rotational images of human anatomy for cardiovascular, vascular and non-vascular, diagnostic and interventional procedures.

Additionally, with the OR table, the angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for image-guided surgical procedures. The OR table is suitable for interventional and surgical procedures.

GMDN Code: 37623

GMDN Description: Stationary angiographic x-ray system, digital

EMDN Code: Z11030102

EMDN Description: STATIONARY ANGIOGRAPHY SYSTEMS FOR ANGIOGRAPHIC AND CARDIOLOGIC STUDIES

Class: IIb

Classification rule (Annex VIII): Rules 10

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:



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- Technical Documentation reference: DOC2680737, of the product to which this declaration relates.
 - EC certificate N° 38746:
 - 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 n°0459)
 - List of common specifications applied and in relation to which conformity is declared:
 - EN 60601-2-43:2010+A1:2018
 - EN IEC 60601-2-46:2019 when applicable
 - EN 62304:2006+A1:2015
 - EN 60601-1-6:2010+A1:2015
 - EN 62366-1:2015+A1:2020
 - EN ISO 10993-1:2020
 - EN ISO 20417:2021
 - EN ISO 15223-1:2021

SIGNATURE:

Date of issue:

Place of issue: Buc

Name: Philip MALCA

Function: GEHC Interventional Regulatory Affairs Director

Signature:

End of Document

Certificat/Certificate:

N° 38746 rev. 2

Délivré le/Issued on:

October 6th, 2022

Certificat délivré à/Certificate issued to: **GE MEDICAL SYSTEMS SCS****283 RUE DE LA MINIERE****78530 BUC FRANCE**

SRN: FR-MF-000000687

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) d'audit du système de gestion de la qualité référencé(s) P601630, P602639, le système de gestion de la qualité est conforme aux dispositions pertinentes du règlement (UE) 2017/745 pour les produits suivants :

GMED certifies that, on the basis of the results listed in the quality management system audit report(s) referenced P601630, P602639, the quality management system complies with the relevant provisions of the regulation (EU) 2017/745 for the following products:

Dispositif ou système d'angiographie digital incluant les accessoires et logiciels associés

Digital angiography device or system including accessories and related software

Voir détails sur addendum / See addendum for additional information

Aux fins de la mise sur le marché de dispositifs de classe IIb implantables et/ou de classe III, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/745 est requis.

For the purpose of placing on the market implantable class IIb and / or class III devices, another certificate issued in accordance with the provisions of the regulation (EU) 2017/745 is required.

Début de validité /Effective date: October 6th, 2022 (included)**Valable jusqu'au /Expiry date:** April 15th, 2026 (included)

La validité du présent certificat est conditionnée au respect des obligations qui découlent du système de gestion de la qualité approuvé et de la surveillance effectuée par l'organisme notifié prévue par le règlement. Ce certificat est lié par les conditions du contrat.

The validity of this certificate is subject to compliance with the obligations arising from the approved quality management system and from the surveillance carried out by the notified body as required by the regulation. This certificate is bound by the conditions of the contract.



Lionel DREUX
President

1. Identification des sites / Identification of sites:

GE MEDICAL SYSTEMS SCS
 283 RUE DE LA MINIERE, 78530 BUC, FRANCE

2. Identification des dispositifs / Identification of devices:

Nom du dispositif médical <i>Medical device name</i>	Nom commercial <i>Commercial name</i>	Destination (DM classe IIb uniquement) <i>Intended use (MD Class IIb only)</i>	Classe du DM <i>MD Class</i>
Allia IGS 3	Allia IGS 3	Stationary angiographic x-ray system, digital	IIb
Allia IGS 5	Allia IGS 5		
Allia IGS 7	Allia IGS 7		
Allia IGS 7 OR	Allia IGS 7 OR		
EVARVision	EVARVision	X-ray system, diagnostic, fluoroscopic, angiographic, application program software	
HeartVision 2	HeartVision 2		
TrackVision 2	TrackVision 2		
Vision 2	Vision 2		

3. Historique du certificat / Certificate history:

Référence au certificat précédent <i>Reference to the preceeding certificate</i>	Date de délivrance <i>Date of issue</i>	Modifications apportées <i>Identification of the changes</i>
38746 rev. 0 38746 rev. 0	25/01/2022 01/25/2022	Ajout d'un dispositif au sein d'une catégorie de dispositif existante <i>Addition of a device to the existing device's category</i>
38746 rev. 1 38746 rev. 1	22/04/2022 04/22/2022	Mise à jour du nom de dispositif médical <i>Update of medical device name</i>



GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

GE MEDICAL SYSTEMS SCS
283 RUE DE LA MINIERE

78530 BUC FRANCE

pour les activités
for the activities

**Conception, développement, fabrication, contrôle final et distribution de
dispositifs ou systèmes de radiodiagnostic comprenant les systèmes d'angiographie,
mammographie, station de travail et logiciels associés et des gaines équipées (Voir addendum)**

*Design, development, manufacture, final test and distribution of radiodiagnostic devices or systems including
angiographic systems, mammographic systems, workstation and associated software and
X-ray tube assemblies (See addendum)*

réalisées sur le(s) site(s) de
performed on the location(s) of

**GE MEDICAL SYSTEMS SCS
283 RUE DE LA MINIERE - 78530 BUC - FRA
GE MEDICAL SYSTEMS SCS
128 rue des Chardonnerets - ZAC de Paris Nord 2 - 93290 TREMBLAY EN FRANCE - FRA**

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485 : 2016 - NF EN ISO 13485 : 2016

Début de validité / Effective date : November 13th, 2023 (included)

Valable jusqu'au / Expiry date : December 20th, 2026 (included)

Etabli le / Issued on : November 13th, 2023



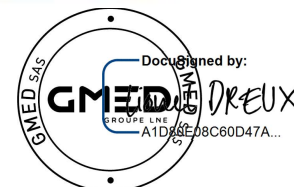
GMED_SQ-F-0007-2018

Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 12957-9

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 12957-8



Lionel DREUX
President

Résumé des activités couvertes par le certificat :

Summary of activities covered by the certificate :

French version :

Conception, développement, fabrication, contrôle final et distribution de dispositifs ou systèmes de radiodiagnostic comprenant les systèmes d'angiographie, mammographie, station de travail et logiciels associés et des gaines équipées

English version :

Design, development, manufacture, final test and distribution of radiodiagnostic devices or systems including angiographic systems, mammographic systems, workstation and associated software and X-ray tube assemblies

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites :

**GE MEDICAL SYSTEMS SCS
283 RUE DE LA MINIERE
78530 BUC
FRANCE**

French version :

Conception, développement, fabrication, contrôle final et distribution de dispositifs ou systèmes de radiodiagnostic comprenant les systèmes d'angiographie, mammographie, station de travail et logiciels associés et des gaines équipées

English version :

Design, development, manufacture, final test and distribution of radiodiagnostic devices or systems including angiographic systems, mammographic systems, workstation and associated software and X-ray tube assemblies

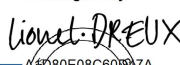
**GE MEDICAL SYSTEMS SCS
128 rue des Chardonnerets
ZAC de Paris Nord 2
93290 TREMBLAY EN FRANCE
FRANCE**

French version :

Distribution de dispositifs ou systèmes de radiodiagnostic comprenant les systèmes d'angiographie, mammographie, station de travail et logiciels associés

English version :

Distribution of radiodiagnostic devices or systems including angiographic systems, mammographic systems, workstation and associated software

DocuSigned by:

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**Lionel DREUX
President**

GMED certifică că sistemul de management al calității dezvoltat de

GE MEDICAL SYSTEMS SCS
283 RUE DE LA MINIERE

78530 BUC FRANȚA
pentru activitățile
pentru activitățile

Proiectarea, dezvoltarea, fabricarea, testarea finală și distribuția de dispozitive sau sisteme de radiodiagnostic, inclusiv sisteme angiografice, sisteme mamografice, stații de lucru și software asociat și ansambluri de tuburi cu raze X (Consultați act adițional)

efectuate în locația (locațiile)

GE MEDICAL SYSTEMS SCS
283 RUE DE LA MINIERE - 78530 BUC - FRA
GE MEDICAL SYSTEMS SCS
128 rue des Chardonnerets - ZAC de Paris Nord 2 - 93290 TREMBLAY EN FRANȚA - FRA

respectă cerințele standardelor internaționale

ISO 13485: 2016 - NF EN ISO 13485 : 2016

Data intrării în vigoare: 13 noiembrie 2023 (inclusiv)

Data expirării: 20 decembrie 2026 (inclusiv)

Emis la: 13 noiembrie 2023

Rezumatul activităților acoperite de certificat:

Versiune în limba engleză:

Proiectarea, dezvoltarea, fabricarea, testarea finală și distribuția de dispozitive sau sisteme de radiodiagnostic, inclusiv sisteme angiografice, sisteme mamografice, stații de lucru și software asociat și ansambluri de tuburi cu raze X

Acest certificat acoperă următoarele activități și locații:

**GE MEDICAL SYSTEMS SCS
283 RUE DE LA MINIERE
78530 BUC
FRANȚA**

Versiune în limba engleză:

Proiectarea, dezvoltarea, fabricarea, testarea finală și distribuția de dispozitive sau sisteme de radiodiagnostic, inclusiv sisteme angiografice, sisteme mamografice, stații de lucru și software asociat și ansambluri de tuburi cu raze X

**GE MEDICAL SYSTEMS SCS
128 rue des Chardonnerets
ZAC de Paris Nord 2
93290 TREMBLAY EN FRANȚA
FRANȚA**

Versiune în limba engleză:

Distribuția de dispozitive sau sisteme de radiodiagnostic, inclusiv sisteme angiografice, sisteme mamografice, stații de lucru și software asociat

DocuSigned by:

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Lionel DREUX
Președinte

Subsemnata, **Lascu Raluca Teodora**, interpret și traducător autorizat pentru limbile străine engleză și franceză, în temeiul Autorizației nr. 20862 din data de 12/11/2007, eliberată de Ministerul Justiției din România, certific exactitatea traducerii efectuate din limba engleza în limba română , că textul prezentat a fost tradus complet, fără omisiuni, și că, prin traducere, înscrisului nu i-au fost denaturate conținutul și sensul.

