

## **ATTESTATION CE / EC CERTIFICATE**

**Approbation du Système Complet d'Assurance Qualité / Approval of full Quality Assurance System**

**ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux**

**ANNEX II excluding section 4 DIRECTIVE 93/42/EEC concerning medical devices**

**Pour les dispositifs de classe III, un certificat CE de conception est requis**

**For class III devices, a EC design certificate is required**

**Fabricant / Manufacturer**

**GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC  
8200 WEST TOWER AVENUE  
MILWAUKEE, WISCONSIN 53223 UNITED STATES**

**Catégorie du(des) dispositif(s) / Device(s) category**

**Equipements de cardiologie et systèmes de surveillance de patients  
Systèmes de surveillance clinique et systèmes de télémétrie médicale  
Baie de cathétérisme et/ou d'électrophysiologie  
Moniteurs cardiaques et leurs accessoires  
Moniteurs de surveillance patient  
Systèmes d'électrocardiographie et de surveillance de patients**

*Cardiology equipment and patient monitoring systems  
Clinical Monitoring Systems and Medical Telemetry Systems  
Catheterization and/or Electrophysiology lab System  
Cardiology monitors and accessories  
Patient monitors  
Electrocardiographs and patient monitoring systems*

**Voir document complémentaire GMED / See GMED additional document  
n° 38313**

**GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P602818, P601202, le système d'assurance qualité – pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.**

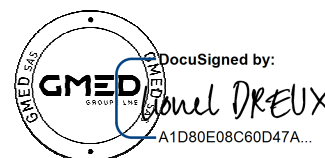
*GMED certifies that, on the basis of the results contained in the file referenced P602818, P601202, the quality system - for design, manufacturing and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.*

**La validité du présent certificat est soumise à une vérification périodique ou imprévue.**

*The validity of the certificate is subject to periodic or unexpected verification.*

**Début de validité / Effective date : June 8<sup>th</sup>, 2021 (included)**

**Valable jusqu'au / Expiry date : May 26<sup>th</sup>, 2024 (included)**



DocuSigned by:  
**Lionel DREUX**  
A1D80E08C60D47A...

**Lionel DREUX  
Certification Director**

**Ce document complémentaire GMED n° 38313 rev. 1 atteste de la validité du certificat CE N° 7550 rev. 22 au regard des informations listées ci-dessous.**

*This GMED additional document n° 38313 rev. 1 attests to the validity of EC certificate N° 7550 rev. 22 with regard to the information listed below.*

**Fabricant / Manufacturer:**

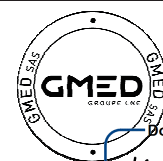
**GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC  
8200 WEST TOWER AVENUE  
MILWAUKEE, WISCONSIN 53223 UNITED STATES**

**Identification des dispositifs / Identification of devices**

Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM <i>MD class</i>
Patient monitor, Central unit	Central Station (CSCS)	IIb
Patient monitor module, multiparameter	Patient Data Module (PDM)	IIb
Patient monitor, multiparameter	B20	IIb
Patient monitor, multiparameter	B40	IIb
Patient Monitor, multiparameter	B105	IIb
Patient Monitor, multiparameter	B125	IIb
Patient Monitor, multiparameter	CARESCAPE ONE	IIb
Transportable physiologic monitoring system	V100	IIb
Telemetry system, electrocardiograph	ApexPro Telemetry System	IIb
Clinical monitoring systems	Unity Network ID	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	MacLab	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	CardioLab	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	ComboLab	IIb

**GMED 0459**

GMED - 38313 rev. 1  
Renouvelle le document n° 38313 rev. 0



DocuSigned by:

*Lionel DREUX*

A1D80E08C60D47A...

**Lionel DREUX**  
Certification Director

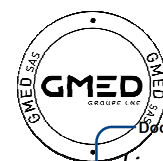
Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM <i>MD class</i>
Electrocardiograph, Holter analyzer	Mars	Ila
Electrocardiograph, Holter analyzer	Mars SP4	Ila
Information system software, application program, cardiology	MUSE – SW Only	Ila
Information system software, application program, cardiology	CV Web	Ila
ECG Acquisition module	CAM 14V2	Ila
ECG Acquisition module	CAM HD	Ila
Interpretive multichannel electrocardiograph	MAC 2000	Ila
Interpretive multichannel electrocardiograph	MAC 600	Ila
Interpretive multichannel electrocardiograph	MAC VU360	Ila
Stress exercise monitoring system, cardiac	Case	Ila
Stress exercise monitoring system, cardiac	Cardiosoft / CS	Ila
Stress exercise monitoring system, cardiac	Cardiosoft / CS WIN8	Ila
Electrocardiograph, Electrodes	KISS	Ila

### Site couvert et Activités / Location and Activities

Site / Location	Activités / Activities
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC 8200 WEST TOWER AVENUE MILWAUKEE, WISCONSIN 53223 - USA	<b>Siège social – responsable de la mise sur le marché</b> <b>Conception, fabrication et contrôle final</b> <i>Headquarters – legal manufacturer</i> <i>Design, manufacture and final control</i>

**GMED 0459**

GMED - 38313 rev. 1  
Renouvelle le document n° 38313 rev. 0



DocuSigned by:

Lionel DREUX

A1D80E08C60D47A...

**Lionel DREUX**  
Certification Director