GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* N° 7550 rev. 20
Délivrée à Paris le 6 mars 2020
Issued in Paris on March 6th, 2020

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 détails sur addendum / *See attachment for additional information*

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P178961, 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 P178961, P601202, the quality system - for design, manufacturing and final inspection - of medical devices listed here aboved 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 :* **January 7th, 2020 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

GMED – 7550 rev 20
Annule et remplace le certificat 7550-19

GMED_Jq04-F- V0–07-2018

GMED GROUPE LNE

Addendum à l'attestation N° 7550 rev. 20 page 1 / 2
Addendum of the certificate N° 7550 rev. 20
Dossier / *File* N° P178961, P601202

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Produit** *Product* **Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
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 SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

GMED
GROUPE LNE

Addendum à l'attestation N° 7550 rev. 20 **page 2 / 2**
Addendum of the certificate N° 7550 rev. 20
Dossier / *File* N° P178961, P601202

Identification des dispositifs / *Identification of devices*

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

Identification du site couvert et des activités / *Identification of location and activities*

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

GMED 0459

On behalf of the President
Béatrice LYS
Technical Director

GE HMEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC
8200 WEST TOWER AVENUE
MILWAUKEE, WISCONSIN 53223
USA

To the attention of Mr Bob TRISCARI

Paris, March 6th, 2020

Registered Mail with Return Receipt

Certification Project Manager : Michel GREC
Tel. : + 33 1 40 43 39 35
Fax : + 33 1 40 43 37 37
E-mail: michel.grec@lne-gmed.com

Re : EC certificate
Ref. : MMA/MGR/BLY/845/2020

Dear Mr TRISCARI,

After receipt of our letter referenced MMA/MGR/BLY/049/2020 dated January 7th, 2020, further to your e-mails of March 3rd, 2020 and according to your request to restore only the CE marking of the product "B20" with GMED SAS due to a miss communication by your company, we notify you the continuation of the product B20 on your EC certificate N° 7550 according to the annex II excluding section 4 of the directive 93/42/EEC.

You will find attached the EC certificate N° 7550 rev 20 duly modified.

Furthermore, we remind you that following the "Code de la Santé Publique" – articles R 5211-12 and R5211-17 - which transposes the European Directives into French law, it is your responsibility to assure that only medical devices which are in compliance with requirements specified in these articles can bear the CE mark and can be put on the European market.

Yours sincerely,

Béatrice LYS
Technical Director

Encs. : 1 EC certificate N° 7550 rev. 20 and its addendum (2 pages)

ATETASTAS/ *SERTIFIKATAS* **N° 7550 rev. 20**
Išduota Paryžiuje kovo 6st, 2020

ATSTATCIJA CE / *ES SERTIFIKATAS*

Approbation du Syst&me Complet d'Assurance Quality / Visiškos kokybės užtikrinimo sistemos kokybės tvirtinimas.
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs medicaux
II PRIEDAS, išskyrus 4 skirsnį. DIREKTYVA 93/42/EEB dėl medicinos prietaisų
Pour les dispositifs de classe III, un certificate CE de conception est requls
III klasės prietaisams reikalingas EB dizaino sertifikatas

Gamintojas (pavadinimas ir adresas)

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC
A General Electric Company, dalis GE Healthcare organizacijos
8200 WEST TOWER AVENUE
MILWAUKEE, WISCONSIN 53223 - JAV

Categorie du(des) dispositif(s) / *Prietaiso(-ų) kategorija*

Equipements de cardiologie et systemes de surveillance de patients Systemes de surveillance clinique et systemes de t6l6metrie medicale Baie de catheterisme et/ou d'electrophysiologie Moniteurs cardiaques et leurs accessoires Moniteurs de surveillance patient Systemes d'electrocardiographie et de surveillance de patients

Kardiologijos įranga ir pacientų stebėjimo sistemos
Klinikinės stebėjimo sistemos ir medicininės telemetrijos sistemos
Kateterizacijos ir / arba elektrofiziologijos laboratorijos sistemos
Kardiologijos monitoriai ir priedai
Pacientų monitoriai
Elektrokardiografai ir pacientų stebėjimo sistemos
Žr. Priedą

GMED attests qua lexamen des resultats figurant dans le rapport reference P178961, P601202 le systeme d'assurance quality - pour la conception, la production et le contrdle final - des dispositifs medicaux enumeres ci-dessus est conforms aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED patvirtina, kad, remiantis rezultatais, esančiais byloje, kuriai daroma nuoroda P178961, P601202, šioje direktyvoje išvardytų medicinos prietaisų kokybės užtikrinimo sistema - projektavimui, gamybai ir galutiniam patikrinimui atitinka Direktyvos 93 reikalavimus / 42 / EEB, II priedas, išskyrus 4 skirsnį.

La validlte du present certificat est soumise a une verification periodique ou imprevue.

Sertifikato galiojimui taikomas periodiškas arba netikėtas patikrinimas.

Debut de validite / *Įsigaliojimo data:* **Sausio 7, 2020 (imtinai)**
Valable jusqu'au / *Galiojimo data :* **Gegužės 26 2024 (imtinai)**

/spaudas/

Prezidento vardu
Beatrice LYS
Technikos direktorius
/parašas/

GMED - 7550 rev. 20
Renouvelle le certificat 7550-19

Addendum a l'attestation N° 7550 rev. 20
Sertifikato papildymas N° 7550 rev. 20
Dossier / *Byla* N° P178961, P601202

Identification des dispositifs / *Prietaisų identifikavimas*

Designation du dispositif / Accessoires marques CE *Įrenginio žymėjimas / ES pažymėti priedai*	**Produit/***Produktas* **Ref commercial du dispositif ou code article** *Įtaiso komercinė nuoroda ar Gaminio kodas*	**Classe du DM** *MD klasė*
Paciento monitorius, Centrinis blokas	**Centrinė stotis (CSCS)**	**IIb**
Paciento monitoriaus modulis, daugiaparametrinis	**Paciento duomenų modulis(PDM)**	**IIb**
Paciento monitorius, daugiaparametrinis	**B20**	**IIb**
Paciento monitorius, daugiaparametrinis	**B40**	**IIb**
Paciento monitoriaus **daugiaparametrinis**	**B105**	**IIb**
Paciento Monitorius, daugiaparametrinis	**B125**	**IIb**
Paciento Monitorius, daugiaparametrinis	**CARESCAPE ONE**	**IIb**
Transportuojama fiziologinė stebėjimo sistema	**V100**	**IIb**
Paciento monitorius, centrinis vienetas	**CIC Pro**	**IIb**
Telemetrijos sistema, elektrokardiografas	**ApexPro Telemetry System**	**IIb**
Klinikinio monitoringo sistema	**Unity Tinklo ID**	**IIb**
Širdies kateterizacijos stebėjimo sistema, Širdies elektrofizologijos analizės sistema	**MacLab**	**IIb**
Širdies kateterizacijos stebėjimo sistema, Širdies elektrofizologijos analizės sistema	**CardioLab**	**IIb**
Širdies kateterizacijos stebėjimo sistema, Širdies elektrofizologijos analizės sistema	**Combo Lab**	**IIb**

/spaudas/ parašas/

GMED 0459

Prezidento vardu
Beatrice LYS
Technikos direktorius
/parašas/

Addendum a l'attestation N° 7550 rev. 16
Sertifikato papildymas N° 7550 rev. 16
Dossier / *Byla* N° P178961-2

Identification des dispositifs / *Įrenginių identifikavimas*

Designation du dispositif / Accessoires marques CE *Įrenginio žymėjimas / ES pažymėti priedai*	**Produit/***Produktas* **Ref commercial du dispositif ou code article** *Įtaiso komercinė nuoroda ar Gaminio kodas*	**Classe du DM** *MD klasė*
Elektrokardiografas, Holterio analizatorius	**Mars**	**IIa**
Elektrokardiografas, Holterio analizatorius	**Mars SP4**	**IIa**
Informacinės sistemos programinė įranga, taikomoji programa, kardiologija	**MUSE - SW tiktai**	**IIa**
Informacinės sistemos programinė įranga, taikomoji programa, kardiologija	**CV Web**	**IIa**
EC6 Įsigijimo modulis	**CAM 14V2**	**IIa**
ECG Įsigijimo modulis	**CAM HD**	**IIa**
Interpretuojamas daugiakanalis elektrokardiografas	**MAC 2000**	**IIa**
Interpretuojamas daugiakanalis elektrokardiografas	**MAC 600**	**IIa**
Interpretuojamas daugiakanalis elektrokardiografas	**MAC VU360**	**IIa**
Streso pratybų stebėjimo sistema, širdies	**Case**	**IIa**
Streso pratybų stebėjimo sistema, širdies	**Cardiosoft / CS**	**IIa**
Streso pratybų stebėjimo sistema, širdies	**Cardiosoft /** ***CS*** **W1N8**	**IIa**
Elektrokardiografas, Elektrodai	**KISS**	**IIa**

/spaudas/parašas/

Vietos ir paslaugų identifikacia

GE MEDICLA SYSTEMS INFORMATION TECHNOLOGIES, INC - 8200 WEST TOWER AVENUE
Milvokis, Viskonsino valstija 53223 - JAV
Buveinė - legalus gamintojas
Dizainas, gamyba ir galutinė kontrolė

GMED 0459

Prezidento vardu
Beatrice LYS
Technikos direktorius

*GMED - Supaprastinta akcinė bendrovė, kurios kapitalas 300000 Eur * Organisme Notifie/ Notifikavimo įstaiga. 0459*
*Pagrindinė buveinė: 1, Gaston Boissier - 75015 Paryžius * Tel. 01 40 43 37 00 * gmed.fr*

/parašas

EG-KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

CE 0123

Wir / We	**ergoline GmbH** **Lindenstr. 5** **72475 Bitz (Germany)**
erklären in alleiniger Verantwortung,dass das Medizinprodukt / declare on our own responsibility that the medical device	**Bicycle ergometer "ebike III"**
Modelle / Models	**2017911-301: eBike III Basic** **2017911-303: eBike III Basic with NIBP** **2017911-305: eBike III comfort** **2017911-307: eBike III comfort with NIBP**
und das Zubehör / and the accessories	**2017911-051: ebike III cuff adult std tube 130cm** **2017911-052: ebike III cuff adult small tube 130cm** **2017911-053: ebike III cuff adult large tube 130 cm** **2017911-015: ebike saddle mount infant** **2017911-016: ebike saddle infant** **2017911-017: ebike saddle sport** **2017911-018: ebike saddle mount hor. adjustable** **2017911-019: ebike crank set adjustable** **2017911-044: ebike Velcro for cuff tube** **2017911-131: USB Cable 5m ebike II III to cardiosoft PC** **2018111-340: Spare ebike III COM Module** **2017911-140: Power cord C Euro ebike II III** **2017911-141: Power cord G2 UK ebike II III** **2017911-142: Power cord A US ebike II III** **2017911-144: Power cord M2 South Africa ebike II III** **2017911-145: Power cord I2 Australia ebike II III** **2017911-047: ebike III Comfort Stabilizer plate** **2017911-325: DVD MNL OPR ebike II III** **2017911-130: ebike II III driver CD**
mit den Anforderungen der Richtlinie übereinstimmt / is in conformity with the Directive	**93/42/EWG: Anhang II (ohne 4)** **93/42/ECC: Annex II (excluding 4)**
UMDNS-Code / UMDNS-Code	**10383**
Benannte Stelle / Notified Body:	**TÜV SÜD Product Service GmbH** **Ridlerstr. 65** **80339 München** **Germany**

Konformitätsbewertungs-verfahren / Conformity assessment procedure:	**Anhang II (ohne 4)** **Appendix II (excluding 4)**
Klasse / Class	**IIa**
Klassifizierung nach / Classification according to:	**Anhang IX / Regel 10** **appendix IX / rule 10**

Beginn der Gültigkeit / Begin of the validity:
Datum/Date: 2016-09-15

Ort/City:
Bitz den, 2016-09-15

Axel Bodmer
Qualitätsmanagement / Quality Manager

ergoline GmbH
Lindenstraße 5 • D-72475 Bitz
Tel.: +49(0)7431 • 9894-0

ergoline
MOVING TO HEALTH

ergoline GmbH • Lindenstrasse 5 • 72475 Bitz • Germany

To whom it may concern

January 12th, 2017

Certificate of Relationship

We hereby certify that ergoline GmbH, Lindenstr. 5, 72475 Bitz, Germany,

- Is the manufacturer of the products below,
- Authorizes GE Healthcare to sell, import, distribute, service, manipulate and store Ergoline products,
- Authorizes GE Healthcare to train end users and
- Authorizes GE Healthcare to repair and provide maintenance.

Products:

eBike Basic
eBike Comfort
eBike L
eBike EL
eBike III Basic
eBike III Comfort

Sincerely,

Axel Bodmer

Quality Manager

ergoline GmbH
Lindenstrasse 5
72475 Bitz
Germany
Telefon:
+49 (0)7431 / 9894-0
Telefax:
+49 (0)7431 / 9894-128
email:
info@ergoline.com
Internet:
www.ergoline.com
Geschäftsführer:
Josef de Witt
Dr. Lutz Neumann
Amtsgericht Stuttgart
HRB 401253
Sparkasse Zollernalb
BLZ 653 512 60
Konto 66 109 103
SWIFT-BIC:
SOLADES1BAL
IBAN:
DE02 6535 1260
0066 1091 03
UST-ID (VAT):
DE 216390404

ergoline
MOVING TO HEALTH

EG-KONFORMITATSERKLARUNG / ATITIKTIES DEKLARACIJA

CE 0123

Wir / Mes

ergoline GmbH
Lindenstr. 5
72475 Bitz (Vokietija)

erklaren in alleiniger Verantwortung,dass das Medizinprodukt / savo atsakomybe pareiškiame, kad medicinos prietaisas

Dviratinis ergometras "ebike III"

Modelle / Modeliai

2017911-	**301:**	**eBike III Basic**
2017911-	**303:**	**eBike III Basic with NIBP Basic su NKS**
2017911-	**305:**	**eBike III comfort**
2017911-	**307:**	**eBike III comfort su NKS***

und das Zubehor / ir priedai

2017911 051: ebike III manžetė suaugusiems su standartiniu vamzdeliu 130cm
2017911 052: ebike III manžetė suaugusiems su mažu vamzdeliu 130cm
2017911 -053: ebike III manžetė suaugusiems su storu vamzdeliu 130 cm
2017911-015: ebike balnas montuojamas naujagimiui
2017911-016: ebike balnas naujagimiui
2017911-017: ebike balnas sportinis
2017911-018: ebike balno montavimui reguliuojamam
2017911-019: ebike alkūnės rinkiniui reguliuojamas
2017911 -044: ebike Velcro manžetės vamzdeliui
2017911-131: USB kabelis 5m. ebike II III į cardiosoft PK
2018111-340: Atsarginis ebike III COM Modulis
2017911-140: Maitinimo kabelis C Euro ebike II III
2017911-141: Maitinimo kabelis G2 DB ebike II III
2017911-142: Maitinimo kabelis A JAV ebike II III
2017911-144: Maitinimo kabelis M2 Pietų Afrika ebike II III
2017911-145: Maitinimo kabelis I2 Austrija ebike II III
2017911-047: ebike III Comfort Stabilizavimo plokštė
2017911-325: DVD MNL OPR ebike II III
2017911-130: ebike II III driver CD

mit den Anforderungen der Richtlinie ubereinstimmt / Atitinka Direktyvą **93/42/EWG: Anhang II (ohne 4)**

93/42/EBB: Priedas II (išskyrus 4)

UMDNS-Code / UMDNS-kodas

10383

Benannte Stelle / Notifkavimo Tarnyba:

TUV SUD Product Service GmbH
Ridlerstr. 65 80339 Munchen
Vokietija

*NKS (neinvazinis kraujo spaudimo matavimas)

Konformitatsbewertungs-verfahren / Atitikties įvertinimo procedūra:	**Anhang II (ohne 4) priedas II (išskyrus 4)**
Klasse / Clasė	**IIa**
Klassifizierung nach / Klasifikacija pagal :	**Anhang IX / Regel 10 priedą IX / taisyklė 10**

Beginn der Gültigkeit / Galiojimo pradžia:
Datum/Data: 2016-09-15

Ort/Miestas:
Bitz den, 2016-09-15

Axel Bodmer
Qualitatsmanagement / Kokybės vadybininkas

ergotine GmbH
LindenstraBe 5 • **D**-72475
B'rtz Tel.: +49(0)7431 •
9894-0

∗NKS (neinvazinis kraujo spaudimo matavimas)

ergoline GmbH • Lindenslrasse 5 • 72475 Bitz • Germany

Suinteresuotiems asmenims

sausis 12th, 2017

Santykių Sertifikatas

Šiuo patvirtiname, kad ergoline GmbH, Lindenstr. 5, 72475 Bitz, Vokietija,

- Yra gamintojas produktų pateiktų žemiau,
- Įgalioja GE Healthcare prekiauti, importuoti, paskirstyti, atlikti servisą, manipuliuoti ir laikyti Ergoline produktus,
- Įgalioja GE Healthcare mokyti galutinius vartotojus ir
- Įgalioja GE Healthcare atlikti remonto ir serviso priežiūrą.

Produktai:

eBike Basic

eBike Comfort
eBike L

eBike EL

eBike III Basic
eBike III Comfort

Pagarbiai,

Axel Bodmer

Kokybės

vadybininkas

ergoline GmbH

Lindenstrasse 5
72475 Bitz Vokietija

Telefonas:

+49 (0)7431 / 9894-0

Telefax:

+49 (0)7431 / 9894-128

email:

info@ergoline.com

Internetas:
www.ergoline.com

Geschaftsfuhrer: Josef de Witt Dr. Lutz Neumann

Amtsgericht Stuttgart
HRB401253

Sparkasse Zollernalb BLZ 653 512 60 Konto 66 109 103

SWIFT-BIC:
S0LADES1BAL

IBAN:
DE02 6535 1260 00661091 03

UST-ID (VAT):
DE216390404

∗NKS (neinvazinis kraujo spaudimo matavimas)