

## 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

**Welch Allyn, Inc.**

**4341 State Street Road**

**Skaneateles Falls, NY 13153 UNITED STATES**

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

**Equipement et logiciel électrocardiographiques de diagnostic et de surveillance  
(multi-paramètres)**

*Electrocardiographic diagnostic and monitoring (multi-parameter) hardware and software*

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T000441-3-R, T000441-4-DOCA, T000441-6-DOCR, T000441-7-DOCR, 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 T000441-3-R, T000441-4-DOCA, T000441-6-DOCR, T000441-7-DOCR, 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 : **August 9th, 2019 (included)**

Valable jusqu'au / Expiry date : **June 1st, 2022 (included)**



**Lionel DREUX**  
Certification Director

**Identification des dispositifs / Identification of devices**

Description du Dispositif Médical <i>Medical Device Description</i>	Référence Commerciale du Dispositif Médical <i>Medical Device Commercial Reference Number</i>	Classe du Dispositif Médical <i>Medical Device Class</i>
<b>ELECTROCARDIOGRAPH</b>		
ELI/BUR 150c	ELI-150c- XXX-XXXXX X=A TO Z or 1 to 9 BUR150c-XXX X= A to Z or 1 to 9	IIa
ELI/BUR 230	ELI230- XXX-XXXXX X=A TO Z 34000-030-XXXXX X = 0 to 9 BUR230-XX X= A to Z or 0 to 9	IIa
ELI/BUR 250c	ELI250c- XXX-XXXXX X=A TO Z BUR250c-XXX X= 1 to 9 or A to Z X= 1 to 9 X= A to Z	IIa
ELI/BUR 280	ELI280- XXX-XXXXX X=A TO Z BUR280-XXX X= A to Z or 1 to 9 X= 1 to 9 X= D OR X	IIa
ELI 380	ELI380-XYZZ X= A TO Z Y= A TO Z Y= A TO Z Z= A to Z or 1 to 9	IIa
RSCRIBE	RSCRIBE-5XX-XXXXX RSCRIBE-XXX-XXXXX SCRIBE-5XX-XXXXX X=A to Z or 1 to 9	IIa
ELI PC/WAM PC Kit	41000-029-XX X= 0 to 9 11066-XXX-50 X= 0 to 9	IIa

**GMED 0459**



**Lionel DREUX**  
**Certification Director**

Description du Dispositif Médical <i>Medical Device Description</i>	Référence Commerciale du Dispositif Médical <i>Medical Device Commercial Reference Number</i>	Classe du Dispositif Médical <i>Medical Device Class</i>
<b>HOLTER</b>		
H-SCRIBE/Burdick Vision Express	HSCRIBE-XXX-XXXXX HSCRIBE-5XX-XXXXX MODALITYMGR-5XX-XXXXX HSREV-XXX-XXXXX SCRIBEWS-5XX-XXXXX X=A to Z BURV53H-X X=1 TO 9 HSDWNLD-XXX-XXXXX SCRIBE-5XX-XXXXX X=A to Z HWEBUP-XXX-XXXXX X= A TO Z	IIa
H3+	H3PLUS-XXX-XXXXX X=A TO Z	IIa
H12+	H12PLUS-XXX-XXXXX X=A TO Z	IIa
<b>STRESS EXERCISES</b>		
Q-STRESS/XScribe	Q4X-XXXXXXX Q4X = 0 TO 9 X=0 THROUGH 9 X=A TO Z X=A TO Z X=A TO Z X=A TO Z XX = 00 OR 09 QS-XXX-XXXXX QR-XXX-XXXXX QSERV-XXX-XXXXX X = A to Z XSCRIBE-XXX-XXXXX SCRIBE-5XX-XXXXX MODALITYMGR-5XX-XXXXX SCRIBEWS-5XX-XXXXX XR-XXX-XXXXX XSERV-XXX-XXXXX X=A to Z XSCRIBE-XXX-XXXXX X=A TO Z	IIa

**GMED 0459**



**Lionel DREUX**  
 Certification Director

Description du Dispositif Médical <i>Medical Device Description</i>	Référence Commerciale du Dispositif Médical <i>Medical Device Commercial Reference Number</i>	Classe du Dispositif Médical <i>Medical Device Class</i>
<b>TELEMETRY</b>		
SURVEYOR CENTRAL TELEMETRY SYSTEM	SCSYS- XXX-XXXXX X=A TO Z SCNODE- XXX-XXXXX SCAC-XXX-XXXXX X=A to Z	IIb
SURVEYOR REVIEW	SCREV- XXX-XXXXX X=A TO Z	IIb
S4	S4-P-X X= A to Z S4-Q-XXX-XXX X = A to Z	IIa
<b>PATIENT MONITOR</b>		
S12/S19 PATIENT MONITOR	SUR12- XXX-XXXXX X=A TO Z SUR19- XXX-XXXXX X=A TO Z	IIb
**Where XYZ designates alpha characters denoting system configuration management codes important for post distribution servicing		

**Ce certificat couvre les activités et les sites suivants :**  
*This certificate covers the following activities and sites:*

**Welch Allyn, Inc.**  
 4341 State Street Road  
 Skaneateles Falls, NY 13153 USA

**Siège social / Headquarters**  
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**Welch Allyn, Inc.**  
 7865 North 86th Street  
 Milwaukee, WI 53224 USA

**Conception / Design**  
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**Welch Allyn, Inc.**  
 7900 North 86th Street  
 Milwaukee, WI 53224 USA

**Fabrication, Distribution et contrôle final / Manufacturing, Distribution and Final Control**  
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<b>GMED</b>	<b>0459</b>
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**Lionel DREUX**  
**Certification Director**

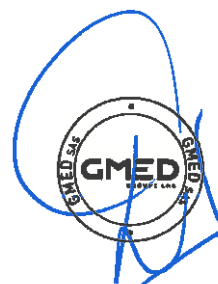
**Welch Allyn, Inc.**  
Via G. di Vittorio 21/b3 40013  
Castel Maggiore, Bologna, Italy

**Conception / Design**

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**4 sites / 4 sites**

<b>GMED</b>	<b>0459</b>
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**Lionel DREUX**  
Certification Director