

## 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 T000441ER-QA5, T001108-P2-DOCR, T001108-P3-DOCR, T001108-P4-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 T000441ER-QA5, T001108-P2-DOCR, T001108-P3-DOCR, T001108-P4-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 : **September 15th, 2020 (included)**

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



On behalf of the President

**Béatrice LYS**

Technical Director

DocuSigned by:

*Beatrice Lys*

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**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>
<i>ELECTROCARDIOGRAPH</i>		
ELI 150c	ELI-150c- XXX-XXXXX X=A TO Z or 1 to 9	IIa
ELI 230	ELI230- XXX-XXXXX X=A TO Z	IIa
ELI 250c	ELI250c- XXX-XXXXX X=A TO Z	IIa
ELI 280	ELI280- XXX-XXXXX X=A TO Z	IIa

<b>GMED</b>	<b>0459</b>
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**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**

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*Beatrice Lys*  
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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>
ELI 380	ELI380-XYZZ X= A TO Z Y = A TO Z Z= A TO Z or 1 to 9	IIa
RSCRIBE	RSCRIBE-XXX-XXXXX RSCRIBE LITE 11120-XXX-50 X= A to Z or 1 to 9	IIa
ELI PC/WAM PC Kit	41000-029-XX X= 0 to 9	IIa
<b>HOLTER</b>		
HSCRIBE/Burdick Vision Express	HSCRIBE-XXX-XXXXX HSERV-XXX-XXXXX X =A to Z  BURV53H-X X=1 TO 9  HSCRIBWS-XXX-XXXXX X= A to Z or 1 to 9	IIa
H3+	H3PLUS-XXX-XXXXX X=A TO Z	IIa
H12+	H12PLUS-XXX-XXXXX	IIa

**GMED 0459**



**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**

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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>
		X=A TO Z
<b>STRESS EXERCISES</b>		
Q STRESS/XScribe	QS-XXX-XXXXX QR-XXX-XXXXX QSERV-XXX-XXXXX XSCRIBE-XXX-XXXXXX XR-XXX-XXXXX XSERV-XXX-XXXXX XScribe CP 41000-030-XX X=A to Z	IIa
<b>TELEMETRY</b>		
SURVEYOR CENTRAL SYSTEM	SCSYS- XXX-XXXXX X=A TO Z SCNODE- XXX-XXXXX SCAC-XXX-XXXXX SCREV- XXX-XXXXX X=A to Z	IIb
S4	S4-P-X X= A to Z S4-Q-XXX-XXX X = A to Z	IIb
<b>PATIENT MONITOR</b>		
S12/S19 PATIENT MONITOR	SUR12- XXX-XXXXX X=A TO Z SUR19- XXX-XXXXX X=A TO Z	IIb
<b>ACQUISITION MODULES</b>		
AM12, AM12Q, AM15	AM12 – 41000-032-XX; 9293-048-XX AM12Q – 9293-062-XX AM15E – 9293-063-XX	IIa
WAM, WAM PC	WAM - 30012-019-XX; 41000-31-XX; 41000-36-XX WAM PC - 30012-020-XX; 41000-029-XX	
AM12M	AM12M – 9293-065-XX	IIb
**Where X, Y, Z designates alpha characters denoting system configuration management codes important for post distribution servicing		

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On behalf of the President  
**Béatrice LYS**  
 Technical Director

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*Beatrice Lys*  
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**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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**Mortara Instrument Europe SRL**

Via G. di Vittorio 21/b3 40013  
Castel Maggiore, Bologna, Italy

**Conception / Design**

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**4 sites / 4 sites**

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**Technical Director**

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