



## **DECLARATION OF CONFORMITY**

(in accordance with ISO/IEC 17050-1)

We declare, under our sole responsibility, that the product listed below conforms to the provisions of:

- the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- the Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment
- the Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

(копа)	
Manufacturer's Name and Business Address:	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA
EC REP	Regulatory Affairs Representative Welch Allyn Limited Navan Business Park, Dublin Road Navan, Co. Meath C15 AW22 Ireland
Product Name <sup>1,3</sup> :	XScribe Stress Exercise Testing System Software Kit
<b>REF</b> 1,3	XSCRIBE-XXX-XXXXX, XSCRIBE-5XX-XXXXX, 41000-XXX-XX (X designates alpha characters denoting system configuration management codes important for post distribution servicing)
# 1,3	901144 CARDIAC STRESS TESTING SYSTEM
Medical Device Conformity Assessment Route Annex <sup>1</sup> :	II
Medical Device Classification <sup>1</sup> :	IIa
Medical Device Classification Rules <sup>1</sup> :	10
GMDN Code and Term <sup>1</sup> :	35447 – Stress exercise monitoring system computer

<sup>&</sup>lt;sup>1</sup> applicable to the medical device directive, 93/42/EEC

<sup>&</sup>lt;sup>2</sup> applicable to the radio equipment directive, 2014/53/EU

<sup>&</sup>lt;sup>3</sup> applicable to the RoHS directive, 2011/65/EU



SAP DIR: M0238.047 Version: R Page 2 of 3

Notified Body <sup>1</sup> : (CE 0459)	LNE G-MED, 1, rue Gaston Boissier 75015 Paris France EC-certificate No. 35913					
Standards Applied	Number	Title				
	EN 50581 <sup>3</sup>	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances				
	EN/IEC 62304 <sup>1</sup>	Medical Device Software – Software Life Cycle Processes				
	EN/IEC 60601-1 <sup>1</sup>	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance				
	EN/IEC 60601-1- 2 <sup>1</sup>	Medical electrical equipment - Part 1-2: General Requirements for Safety — Collateral Standard: Electromagnetic Compatibility — Requirements and Tests				
	EN/IEC 62366 <sup>1</sup>	Medical devices – Application of Usability Engineering to Medical Devices				
	EN/IEC 60601-1-6 <sup>1</sup>	Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability				
	EN/IEC 60601-2- 25 <sup>1</sup>	Medical Electrical Equipment. Part 2 25: Particular requirements for the basic safety and essential requirements of electrocardiographs				
	ETSI EN 301 489 -1 <sup>2</sup>	Electromagnetic compatibility and Radio Spectrum Matters, Part1: Common technical requirements				
	ETSI EN 300 440 -2 <sup>2</sup>	Electromagnetic compatibility and Radio Spectrum Matters				
	ETSI EN 300 328 <sup>2</sup>	Electromagnetic compatibility and Radio Spectrum Matters, Wideband transmission systems; Data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques				

 $<sup>^{\</sup>rm l}$  applicable to the medical device directive, 93/42/EEC  $^{\rm 2}$  applicable to the radio equipment directive, 2014/53/EU  $^{\rm 3}$  applicable to the RoHS directive, 2011/65/EU



SAP DIR: M0238.047 Version: R

Page 3 of 3

Authorised Signatory:

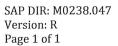
Mark Elliott,

Director Quality Assurance

Date Milwaukee, Wisconsin, USA Place of Issue

<sup>&</sup>lt;sup>1</sup> applicable to the medical device directive, 93/42/EEC

 <sup>&</sup>lt;sup>2</sup> applicable to the radio equipment directive, 2014/53/EU
 <sup>3</sup> applicable to the RoHS directive, 2011/65/EU





Document Change History

Version	Description	Author	Date
P	Initial Release in new format	Marco Manduchi	2019-08-16
		Steven Co	
		Michael Lippold	
R	Updated EC Rep Address	Michael Lippold	2019-10-01