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 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)

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[1,2]:	H12+
REF [1,2]	901141 – HOLTER RECORDER The H12+ comes in different configurations H12PLUS-XXX-XXXXX Where "X" can be a letter from A to Z representing the following: H12PLUS - [Model] [Language] [Power] - [Option1] [Option2] [Option3] [Option4] [Option5]
# [1,2]	901141 – HOLTER RECORDER
Medical Device Conformity Assessment Route Annex[1]:	II
Medical Device Classification[1]:	IIa
Medical Device Classification Rules[1]:	10
GMDN Code and Term[1]:	35162 - Electrocardiographic long-term ambulatory recorder

[1] applicable to the medical device directive, 93/42/EEC
[2] applicable to the RoHS directive, 2011/65/EU

Notified Body[1]: (CE 0459)	LNE G-MED, 1, rue Gaston Boissier 75015 Paris France EC-certificate No. 35913	
Standards Applied (Standards are applicable to the medical device directive, unless otherwise indicated):	Number	Title
	EN 50581[2]	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
	EN/IEC 62304[1]	Medical Device Software – Software Life Cycle Processes
	EN/IEC 60601-1[1]	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
	EN/IEC 60601-1-2[1]	Medical electrical equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
	EN/IEC 60601-1-6[1]	Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability
	EN/IEC 60601-2-47[1]	Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

Authorised Signatory:

Mark Elliott

Mark Elliott,
Director Quality Assurance

07-OCT-2019
Date

Milwaukee, Wisconsin, USA
Place of Issue

[1] applicable to the medical device directive, 93/42/EEC
[2] applicable to the RoHS directive, 2011/65/EU

Document Change History

Version	Description	Author	Date
A	Initial Release	Marco Manduchi Steven Co Michael Lippold	2019-08-16
B	Updated EC Rep Address	Michael Lippold	2019-10-01