DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

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

- European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, and
- 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 as amended by Commission Delegated Directive (EU) 2015/863 of 31 March 2015 (RoHS3).

Document Number **M0238.123**	Version **F**	
Product Name	H12+	
Manufacturer's Name and Business Address	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	SRN: US-MF-000013394
EC Certificate Declaration of Conformity Validity	EC Certificate 35913 Expiry Date: 2024-05-26	
EC REP	Welch Allyn Limited Navan Business Park, Dublin Road Navan Co. Meath C15 AW22 Ireland	SRN: IE-AR-000000768
REF #	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]	
	901141 – HOLTER RECORDER	
Radio equipment	N/A	

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Object of the declaration	 **H12+**
Accessories and components	See Appendix A
Medical Device Conformity Assessment Route Annex	Annex II
Medical Device Classification	IIa
Medical Device Classification Rule	Rule(s) 10
Standards	See Appendix B
GMDN Code and Term	35162 - Electrocardiographic ambulatory recorder
UMDNS Code and Term	18361 - Electrocardiographs, Ambulatory, Continuous
Notified Body	GMED SAS, 1, rue Gaston Boissier 75015 Paris France Notified Body Number: 0459

Authorised Signatory

_____ ____06 MAR 2023_____ St. Paul MN, USA

Mary Donlin
Senior Regulatory Manager
Regulatory Affairs

Date

Place of Issue

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Appendix A: Accessories and Components

SKU	Description
N/A	N/A

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Appendix B: Standards and Common Specifications

Standards Applied	Number	Version/Date of Issue	Title
Directive 93/42/EEC	EN 60601-1	2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN 60601-1-6	2015	Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability
	EN 60601-2-47	2015	Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
	EN 62304	2015	Medical Device Software – Software Life Cycle Processes
	ISO 13485	2016	Medical devices - Quality management systems Requirements for regulatory purposes
	ISO EN 15223-1	2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1 General Requirements
	EN ISO 14971	2019	Medical devices – Application of risk management to medical devices
	EN ISO 20417	2021	Medical devices – Information to be supplied by the manufacturer
Directive 2011/65/EU + (EU) 2015/863	EN IEC 63000	2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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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
C	RoHS3	P. Oris	2021-07-20
D	Release in new format. Modify ROHS statement. Remove IEC standards. Add ISO 13485, ISO EN 15223-1.	S. Co	2021-10-21
E	Updated GMED Address to match NANDO listing Updated EN ISO 15223-1:2021, EN ISO 14971:2019, and EN 20417:2021	S. Loose	2022-08-16
F	Removed 60601-1-2. Updated 60601-1-6 Date.	S. Sokn	2023-03-03