

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 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, 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 **M0238.092**

 Version **S**

Product Name

ELI 230

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



 Welch Allyn Limited
 Navan Business Park, Dublin Road
 Navan Co. Meath
 C15 AW22 Ireland

SRN: IE-AR-000000768




 The ELI230 comes in different configurations
 ELI230-XXX-XXXXX
 Where "X" can be a letter from A to Z representing the following:
 ELI230 - [Model] [Power Cord] [Patient Cable Leadset] - [Option1] [Option2] [Option3]
 [Option4] [Option5]

 Radio configurations:
 WAM/UTK
 ELI230-~~X~~xx-xxxxx Model A

901130 – ELECTROCARDIOGRAPH

Radio equipment

WAM and UTK

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Object of the declaration	 <p style="text-align: center;">ELI 230</p>
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	16231 - Electrocardiograph, professional, multichannel
UMDNS Code and Term	16231 - Electrocardiographs, Multichannel, Interpretive
Notified Body	G-MED SAS 1, rue Gaston Boissier 75015 Paris France Notified Body Number: 0459

Authorised Signatory

Mary Donlin
Senior Regulatory Manager

Date

Minneapolis MN, USA
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 60601-1-2	2015	Medical electrical equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
	EN 60601-1-6	2015	Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability
	EN 60601-2-25	2015	Medical Electrical Equipment. Part 2 25: Particular requirements for the basic safety and essential requirements of electrocardiographs
	EN 62304	2015	Medical Device Software – Software Life Cycle Processes
	EN 62366-1	2020	Medical devices – Application of Usability Engineering to Medical Devices
	ISO 13485	2016	Medical devices - Quality management systems Requirements for regulatory purposes
	EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
	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 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
L	Initial Release	Marco Manduchi Steven Co Michael Lippold	2019-08-16
M	Updated EC Rep Address	Michael Lippold	2019-10-01
N	RoHS3	P. Oris	2021-07-20
O	Not Used	N/A	N/A
P	Release in new format. Modify ROHS statement. Remove IEC standards. Add UMDNS. Add ISO 13485, ISO EN 15223-1.	S. Co	2021-10-21
Q	Not used		
R	Changed GMED name and address to match NANDO. Update EN ISO 15223-1 to 2021 version. Add EN ISO 14971:2019. Add EN ISO 20417:2021.	S.Co	18-AUG-2022
S	Updated Dates for 60601-1-6; 62366-1	S. Sokn	03-MAR-2023