# 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:

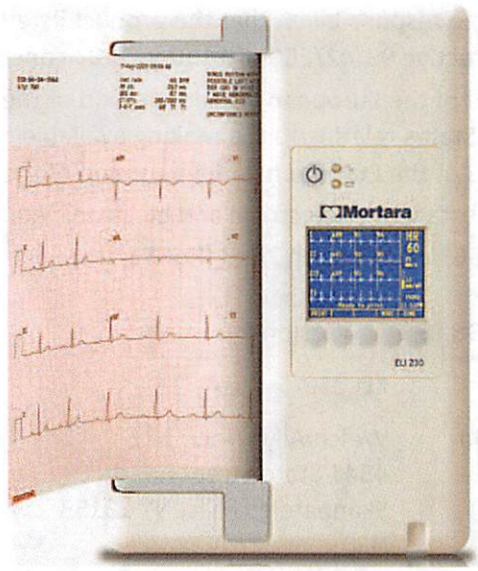
- European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, and
- Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment, and
- Directive 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 **P**

| | | |
|---|---|---|
| Product Name | ELI 230 | |
| Manufacturer's Name and Business Address | Welch Allyn, Inc.<br>4341 State Street Road<br>Skaneateles Falls, NY 13153<br>USA | SRN: US-MF-000013394 |
| EC Certificate Declaration of Conformity Validity | EC Certificate 35913<br>Expiry Date: 2024-05-26 | |
| EC REP | Welch Allyn Limited<br>Navan Business Park, Dublin Road<br>Navan Co. Meath<br>C15 AW22 Ireland | SRN: IE-AR-000000768 |
| REF<br># | The ELI230 comes in different configurations<br>ELI230-XXX-XXXXX<br>Where "X" can be a letter from A to Z representing the following:<br>ELI230 - [Model] [Power Cord] [Patient Cable Leadset] - [Option1] [Option2] [Option3] [Option4] [Option5]<br><br>Radio configurations:<br>WAM/UTK<br>ELI230-**X**xx-xxxxx Model A<br><br>901130 – ELECTROCARDIOGRAPH | |
| Radio equipment | WAM and UTK | |

Hillrom™

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

| | |
|---|---|
| Object of the declaration |  <br>ELI 230 |
| 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,<br>1, rue Gaston Boissier<br>75015 Paris<br>France<br>Notified Body Number: 0459 |

**Authorised Signatory**

Hillrom™

**DECLARATION OF CONFORMITY**

(in accordance with ISO/IEC 17050-1)

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

Joshua Kim
Senior Manager
Global Regulatory Affairs

2021·10·21
Date

Skaneateles Falls NY, USA
Place of Issue

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

## Appendix A: Accessories and Components

| SKU | Description |
|---|---|
| N/A | N/A |

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

## 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 | 2010 | 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 | 2015 | Medical devices – Application of Usability Engineering to Medical Devices |
| | ISO 13485 | 2016 | Medical devices - Quality management systems Requirements for regulatory purposes |
| | ISO EN 15223-1 | 2016 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1 General Requirements |
| 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 |