## DECLARATION OF CONFORMITY

Corporate Headquarters  
Welch Allyn, Inc.  
4341 State Street Road,  
Skaneateles Falls, NY 13153 USA  
Phone: 800.535.8663  
Fax: 516.685.3301  
www.welchallyn.com

<table>
<thead>
<tr>
<th>SAP DIR No.</th>
<th>80020143</th>
<th>Version: A</th>
</tr>
</thead>
</table>

**Manufacturer's Name and Address:**  
Welch Allyn, Inc.  
4341 State Street Road  
Skaneateles Falls, NY 13153

I, Paul G Oris. Hereby declare that the below mentioned medical device

(i) complies with all the requirements under the Act;  
(ii) has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and  
(iii) conforms to requirements specified in APPENDIX 1 of Third Schedule on Essential Principles for Safety and Performance of Medical Devices under Medical Devices Regulations 2012.

| Particular of Medical Device(s): | Product name: Welch Allyn Spot Vision Screener  
|---------------------------------|---------------------------------|
| Manufacturing Site: | Brand/model:  
| Welch Allyn, Inc.  
| 4341 State Street Road  
| Skaneateles Falls, NY 13153, USA  
| Country of origin: USA  
| Risk-based Classification: | Class A, rule 12  
| GMDN code | 46390 Visual Screening Analyser  
| Certification Body: | DQS Medizinprodukte GmbH  
| Certificate Number: | 314505 MP2012  
| Issue Date: | 2013-12-09  
| Expiry Date: | 2016-12-08  
| Standards Applied: | EN 60601-1  
| | Medical Electrical equipment – Part 1: General requirements for Safety.  
| | EN 60601-1-2  
| | Medical electrical equipment – Part 1-2: General requirements for safety – Collateral Standard Safety requirements for medical electrical systems.  
| | ISO 15004-2  
| | Ophthalmic instruments-- Fundamental requirements and test methods: Part 2:Light hazard Protection

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from: 03-March-2015.
I fully understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 [Act 737] to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Authorised Signatory:

[Signature]

Paul G. Oris, Regulatory Affairs Representative

2015-03-06
Date (Year-Month-Day)