DECLARATION OF CONFORMITY

Corporate Headquarters
Welch Allyn, Inc.
4341 State Street Road,
Skaneateles Falls, NY 13153 USA
Phone: 800.535.6663 Fax: 315.685.3361
www.welchallyn.com

SAP DIR No.:	80020143 Version: A	
Manufacturer's Name and Business 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 Brand/model: 901029 Vision Screener Country of origin: USA	
Manufacturing Site:	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153, USA	
Risk-based Classification:	Class A, rule 12	
GMDN code	46390 Visual Screening Analyser	
Quality Management System Certificate:	Certification Body: DQS Medizinprodukte GmbH Certificate Number: 314505 MP2012 Issue Date: 2013-12-09 Expiry Date: 2016-12-08 QMS Standard: EN ISO 13485:2012 + AC : 2012	
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.*

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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:

Paul G. Oris, Regulatory Affairs Representative

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