DECLARATION OF CONFORMITY

Corporate Headquarters
Welch Allyn, Inc.
4341 State Street Road,
Skaneateles Falls, NY 13153 USA
Phone: 603.535.8669 Fax: 603.535.8661
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

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)