DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

We declare, under our sole responsibility, that the product listed below conforms to the provisions of:

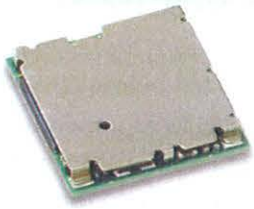
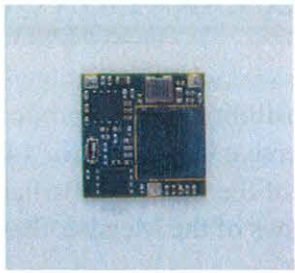
- the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- the Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment
- the 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 (RoHS), including amendment 2015/863.

Manufacturer's Name and Business Address:	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153, USA
EC REP	Regulatory Affairs Representative Welch Allyn Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name[1,3]:	Welch Allyn Spot Vision Screener
REF [1,3]	901029 Vision Screener
# [1,3]	VS100-*, VS100S-* Where * indicates the power cord / country reference

*	Description	*	Description
2	Europe	C	China
3	Israel	G	Argentina
4	United Kingdom	K	South Korea
5	Switzerland	N	India/UAE
66	Australia/New Zealand	P	Thailand
7	South Africa	T	Taiwan
A	Denmark	Y	Italy
B	North America	Z	Brazil

Radio equipment[2]:	Model: WATY

[1] applicable to the medical devices directive, 93/42/EEC
[2] applicable to the radio equipment directive, 2014/53/EU
[3] applicable to the RoHS directive, 2011/65/EU

Object of the declaration[2]:	  Brief Description: IEEE802.11b/g/n standard conformity Transmit speeds: WLAN11b (11/5.5/2/1 Mbps) WLAN11g (54/48/36/24/18/12/9/6Mbps) WLAN11n (7.2/14.4/15/21.7/28.9/30/43. 3/43.3/45/57.8/60/65/72.2/90/120/35/150) Channel Number: 1 to 13 channels RF Output Power 2483.5 MHz 0.075W
Accessories and components[2]:	Not Applicable
Medical Device Conformity Assessment Route Annex[1]:	II
Medical Device Classification[1]:	I(m)
Medical Device Classification Rules[1]:	Class I according to Annex IX, Rule 12 with measurement function (m)
GMDN Code and Term[1]:	46390 Visual Screening Analyser
Notified Body[1]: (CE 0297)	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main EC-certificate No. 314505 MR2

Standards	Number	Title

[1] applicable to the medical devices directive, 93/42/EEC
[2] applicable to the radio equipment directive, 2014/53/EU
[3] applicable to the RoHS directive, 2011/65/EU

Applied (Standards are applicable to the medical device directive, unless otherwise indicated):	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
	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
	EN/IEC 60601-1-6	Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability
	EN/IEC 62304	Medical device software - Software life-cycle processes
	EN/IEC 62366	Medical devices – Application of Usability Engineering to Medical Devices
	EN/ETSI 300 328 V2.1.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband Transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of Directive 2014/53/EU
	EN/ETSI 301 489-1 V2.1.1	EMC and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for Radio Equipment and Services; Part 1: Common Technical Requirements
	EN/ETSI 301 489-17 V3.1.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for 2.4 GHz wideband transmission systems and 5 GHz high performance RLAN equipment
	EN 62479	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)

Authorised Signatory:

Fiona Butler — 2019-05-20 — Navan

Fiona Butler, Manager Regulatory Affairs {EU Authorised Representative} | Date | Place of Issue

[1] applicable to the medical devices directive, 93/42/EEC
[2] applicable to the radio equipment directive, 2014/53/EU
[3] applicable to the RoHS directive, 2011/65/EU