DECLARATION OF CONFORMITY

Waggoner Color Vision Testing, LLC. (DBA Waggoner Diagnostics) located at 16050 Quill Point Dr., Rogers, AR 72756, declares under our sole responsibility that the product(s) to which this declaration relates, listed below, is in conformity with the following standards and other normative documents:

Medical Device	Class
Waggoner Computerized Color Vision Test (Windows, iOS, & Android)	Class I
Waggoner PIP24	Class I
Waggoner Quick Six	Class I
Color Vision Testing Made Easy	Class I
TestingColorVision.com	Class I

EC DIRECTIVE MD DIRECTIVE 93/42/EEC. The Directive is transposed into Ireland's national law. The national legislation implementing the Directive is Statutory Instrument SI2002, No. 618.
CLASS I (RULE 12)

CANADIAN MDR MDR SOR/98-282
CLASS I (RULE 12)

STANDARDS

QUALITY ASSURANCE:	ISO 13485:2016
RISK MANAGEMENT:	ISO 14971:2012
	AAMI TIR32:2004
SAFETY:	IEC 62304:2006
	AAMI TIR32:2004/(R)2016
	IEC 62366-1:2015
	IEC 62366-2:2016

Waggoner Diagnostics is contracting with Authorised European Representative is E C Rep Ltd, 5 Fitzwilliam Square East, Dublin 2, D02 R744, Ireland.

Signature: 

By: Terrace L. Waggoner Jr., CEO
At: Rogers, AR
Date: 2019-06-05