Aughrim Road, Carnew,
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Tel.: 00 353 (0)53 9426742
Fax: 00 353 (0)53 9426051
Email: sales@rehanelectronics.ie
Web: www.rehanelectronics.ie

EC DECLARATION OF CONFORMITY (Rev.2)

1. Manufacturer Details

Name: Rehan Electronics Ltd.

Address: Aughrim Road,,
Carnew,
Co. Wicklow,
Ireland.

Telephone: 00353-53-9426742

Telefax: 00353-53-9426051

2. EU Directives

Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC
Electromagnetic Compatibility (EMC) Directive 2014/30/EU
Low Voltage Directive 2014/35/EU

3. Product Covered by this Declaration

This declaration of conformity is issued under the sole responsibility of the manufacturer named above that the following described equipment is in conformity and the basis for this conformity is described in Point 4 below.

Device Group: Electronic Visual Magnifier

Model/Type: i-SEE HD

4. Basis for Conformity

4.1 The product identified above complies with the requirements of the EU Directives above and conforms to the following normative documents:

EMC	**EN60601-1-2:2012**	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electro Magnetic Compatibility – requirements and tests.
	EN 55032:2014	Electromagnetic Compatibility of multi,edia equipment – Emission requirements. characteristics. Limits and methods of measurement.
	EN 61000-3-2:2014	Electromagnetic Compatibility – Limits. Limits for harmonic current emissions (equipment input current up to and including 16A per phase).
	EN 61000-3-3:2013	Electromagnetic Compatibility – Limitations of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current<= 16A per phase and not subject to conditional connection

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EMC (contd.)	**EN 55024:2010**	Information and Technology Equipment. Immunity characteristics. Limits and methods of measurement.
Safety	**EN 60950-1:2006 +A2: 2013**	Information Technology Equipment – Safety – Part 1: General Requirements
Risk	**EN ISO 14971:2012**	Risk management

Signed by: _____

Seamus Doyle (Director) **Date: 22/02/18**