

Aughrim Road, Carnew. Co. Wicklow, Ireland. Tel.: 00 353 (0)53 9426742 Fax: 00 353 (0)53 9426051

Email: sales@rehanelectronics.ie www.rehanelectronics.ie

EC DECLARATION OF CONFORMITY (Rev.1)

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

Electromagnetic Compatibility (EMC) as part of Medical Devices Directive 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 Handheld Magnifier

Model/Type: Looky 4/4+

4. Basis for Conformity

4.1 The product identified above fulfills the requirements of EMC as part of the Medical Devices Directive. The product is tested and verified in accordance with the following harmonised standard:

EN 60601-1-2:2007

Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -

Requirements and tests

4.2 The product identified above fulfills the requirements of the EMC Directive. The product is tested and verified in accordance with the following harmonised standards:

EN 55011:2009 Class B Industrial, Scientific and Medical (ISM) radio frequency equipment electromagnetic disturbance characteristics. Limits and methods of

measurement.

EN 61000-3-2:2014

+A1:2010

(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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4.3 The product identified above fulfills the requirements of the LVD. The product is tested and verified in accordance with the following harmonised standard:

EN 60950-1:2006

Information Technology Equipment - Safety - Part 1: General Requirements

Signed by:

Seamus Doyle (Director)
Date: 12/04/16