



EC DECLARATION OF CONFORMITY (Rev.1)

1. Manufacturer Details

Name: Rehan Electronics Ltd.
Address: Aughrim Road,,
Carnew,
Co. Wicklow,
Ireland.
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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: Portable TTS Reader

Model/Type: i-Reader

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 +A1:2010 Industrial, Scientific and Medical (ISM) radio frequency equipment electromagnetic disturbance characteristics. Limits and methods of measurement.

EN 61000-3-2:2014 (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 $\leq 16A$ 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

A handwritten signature in black ink, appearing to be "S. Doyle", written over a horizontal line.

Signed by:

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