



# The Standards Institution of Israel

This is to certify that:

**Non-invasive skin treatment platform providing IPL (Intense Light Pulse) and Laser energy**

**Model:** Magma Spark Pro, Magma Spark Plus, Alpha

**Trade Mark:** 

**Applicant:** Formatk Systems Ltd.

**Address Address:** 3 Hayozma St., Tirat Hacarmel, 3903203 Israel

**Manufacturer:** Formatk Systems Ltd.

**Address Address:** 3 Hayozma St., Tirat Hacarmel, 3903203 Israel

**Has been tested by SII and was found to comply with the assessed requirements of :**

**IEC 60601-1 : "Medical Electrical Equipment"**

Part 1: General requirements for basic safety and essential performance 2005 +Am.1 2012

**IEC 60601-1-6: "Medical Electrical Equipment"**

Part 1-6: General requirements for safety – Collateral Standard: Usability 2010 + A1:2013

**IEC60601-2-22: "Medical Electrical Equipment"**

Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment 2007 + A1 2012

**IEC60601-2-57: "Medical Electrical Equipment"**

Part 2: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use (First Edition)

**IEC60825-1: Part 1: Equipment classification and requirements 2007**

**IEC62304: Medical device software**

Software life-cycle processes:  
2006 (First Edition) + A1:2015

**Test results are detailed in SII's TRs No.:**

9812312337, 9812312338, 9812312341, 9812312342, 9812312340, 9812312339

**Certificate No.:** 9812312337

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