

***EU DECLARATION OF CONFORMITY***

*According to Annex IV of the Council Directive 2014/35/EU concerning Low Voltage Directive (LVD);*

**We, El Global Trade Ltd.** (with offices at 13<sup>th</sup> Gibore Israel St., Netanya 4250413, Israel),

**Declare under our sole responsibility that our product:**

***Model: CEL100***

***Trade name: Sensifirm***

***Brand: Sensica***

*SKU – CEL100XXYYZZZ, where XX represents the destination region of the sold product (i.e. UK or EU), YY is a Marketing/ Logistics differentiator (01, 02 etc.) and ZZZ represents the customer code/ brand (e.g. SNS for Sensica).*

**Meets the provisions of the Council Directive 2014/35/EU concerning Low Voltage Directive and Council Directive 2014/30/EU concerning Electromagnetic Compatibility.**

Conformity assessment was performed according to **Annex I and III** of the Directive.

The Sensifirm is an over the counter home use device intended for temporary reduction in the appearance of cellulite and for body firming based on selective electrothermolysis (RF) combined with mechanical vibrational massage. The device is provided non-sterile and does not include measuring functions.

The Sensifirm device is in conformity with the relevant Union harmonization legislation as detailed in the list of tests and standards in the “RD-12039 Sensifirm (cellulite) Traceability Analysis” document and in the table below and meets the LVD Principle Elements for the safety Objectives in Annex I of the Directive.

The Sensifirm device is in conformity with the requirements of Union harmonization legislation, harmonized standards and other standards:

<b>Document</b>	<b>Name</b>
Low Voltage Directive (LVD)	2014/35/EU
EN 60335-1:2012+A11:2014+A13:2017+A1:2019+A14:2019+A2:2019 + A15:2021	Safety of household and similar electrical appliances- Part 1: General requirements
EN 60335-2-23:2003 + A1:2008 + A11:2010 + A2:2015	Safety of household and similar electrical appliances- Part 2-23: Particular requirements for appliances for skin or hair care
Directive 2014/30/EU	Electromagnetic Compatibility (EMC) Directive 2014/30/EU
EN IEC 55014-1:2021	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus. Part 1: Emission
EN IEC 55014-2:2021	Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus. Immunity. Product family standard
EN 62233: 2008	Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposure.

EN 61000-6-3:2007 + A1:2011	Electromagnetic compatibility (EMC) – Part 6-3: Generic standards – Emission standard for residential, commercial and light-industrial environments
EN 61000-6-1:2007	Electromagnetic compatibility (EMC) – Part 6-1: Generic standards- Immunity for residential, commercial and light-industrial environments
EN IEC 61000-3-2:2019 + A1:2021	Electromagnetic compatibility (EMC)- Part 3: Limits Section 2- Limits for Harmonic currents Emissions (equipment input current $\leq 16A$ per phase)
EN 61000-3-3:2013 + A1:2019 + A2:2021	Electromagnetic compatibility (EMC)- Part 3: Limits Section 3: Limitation of Voltage Fluctuations and Flicker in low-voltage supply systems for equipment with rated current $\leq 16A$
EN 301 489-1:2017 (11/2019)	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
EN 301 489-17:2017 (09/2020)	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems
EN 300 328 (07/2019)	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band
EN 50663:2017	Generic standard for assessment of low power electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (10 MHz - 300 GHz)
SVHC 1907/2006 REACH	Substances of Very High Concern (SVHC) under Regulation (EC) No 1907/2006 of REACH
RoHS DIRECTIVE 2011/65/EU and subsequent amendment EU/2015/863	Lead (Pb), Cadmium (Cd), Mercury (Hg), Hexavalent Chromium (CR VI), Polybrominated Biphenyl (PBBs), Polibrominated Diphenyl Ethers (PBDEs), Phthalates (DBP, BBP, DEHP, DIBP)
ErP 2019/1782	Ecodesign requirements for energy-related products.
WEEE	Reuse/Recycling/Recovery Rate of Directive 2012/19/EU

The Sensifirm device was designed, tested, qualified and manufactured by EL Global Trade Ltd. and is imported to the EU by MeSensi Ltd and to Israel by Lifezon Group.

Only the above identified products (all SKUs of CEL100) are covered under this Declaration of Conformity.

**Date of Initial Approval:** September 5<sup>th</sup>, 2017.

**Valid from Batch:** September 2017

**Last Update:** September 14<sup>th</sup>, 2022.

**This Declaration of Conformity is signed and approved by:**

14/09/2022

**Date**



**Sivan Fishman**  
**RA/QA Manager**