# Certificate of Conformity

**GlobalMed Technologies Co.**

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According to MDD 93/42/EEC, the Omnilux Contour™ LED mask is classified as a cosmetic device within the European Union. However, for purposes of safety we have conducted additional testing so that you can be ensured of the safety and efficacy of the Omnilux Contour™ Face system

The Omnilux Contour™ FACE system has been tested to or complies with the following standards;

EN 60601-1:2006/A12:2014. Medical electrical equipment. General requirements for basic safety and essential performance.

EN 60601-1-2:2015 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests

IEC 60601-1-6 2010 AMD12013 Medical Electrical Equipment – Part 1 General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability.

IEC/EN60601-1-11:2015 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC/EN 60601-2-57:2011 Medical electrical equipment. Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

EN 62471:2008 Photobiological Safety of Lamps and Lamp Systems

EN 62366-1:2015 Application of usability engineering to medical devices.

EN ISO 10993-1:2010-04 Biological evaluation of medical devices Part 1: Evaluation and testing

EN ISO 15223-1:2017 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

EN ISO 14971:2012 Medical devices - Application of risk management to medical devices

FCC Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.