



AMI INC.

RM.1412, SJ Techno Ville, 278, Beotkkot-ro, Geumcheon-gu, Seoul, Korea

EC Declaration of Conformity

We herewith declare that the under-mentioned products are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC & Directive 2011/65/EU. All supporting documentation is retained under the premises of the manufacturer.

Product Name (Model Name): Fractional CO₂ Laser (DERMAXEL)

Serial Number: N/A

Classification: Class IIb (Annex IX Rule 9, Council Directive 93/42/EEC as amended by Directive 2007/47/EC)

Conformity Assessment Route: Annex II, Excluding Section 4, Council Directive 93/42/EEC as amended by Directive 2007/47/EC & Directive 2011/65/EU

Notified Body: MIT International Testing Srl
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Applied Standards

EN ISO13485:2012/AC:2012, ISO/TR14969:2004, EN ISO14971:2012, EN980:2008, EN1041:2008, EN60601-1:2006/AC:2010, EN60601-1-2:2007/AC:2010, EN60601-1-6:2010, EN62366:2008, EN60601-2-22:1996, EN62304:2006/AC:2008, IEC/EN60825-1:2007, MEDDEV 2.7.1/Rev.4, MEDDEV 2.12/1 Rev.8, MEDDEV 2.12/2 Rev.2, DIRECTIVE 89/686/EEC

☐ Directive 89/686/EEC is applicable only to the protective goggles

EC Representative: OBELIS S.A
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