

Certificado de Conformidade

Certificate of Compliance ♦ Certificado de Conformidad

Certificado nº: ELM-12385 – First Revision

Certificate #/Certificado nº

Válido até: 29/11/2015

Validity Term/Fecha de Vencimiento

Produto:

Product/Producto

Multifunctional Surgical Light Ceiling Mounted, Wall Mounted Surgical Light and Stand Type Surgical Light
Models: Ceiling Surgical Light Simplex, Ceiling Surgical Light Duplex, Ceiling Surgical Light Triplex, Wall Mounted Light, Ceiling Surgical Light Simplex LED, Ceiling Surgical Light Duplex LED, Ceiling Surgical Light Triplex LED, Wall Mounted Light LED. Stand Type Surgical Light (1B, 13B, 3B, 4B, M31B, M32B, 33B, M4B, M1, M2, LED 1L, LED 3L, LED 4L, LED M4L, LED M1LE, LED M1LEC, LED M1L, LED M1LC, LED 1LE, LED 3LE, LED 4LE, LED M4LE, Parabolic and Parabolic LED).

Voltage and Frequency Rating: 127/220Vac, 50/60 Hz

Power Input: 62VA to 1840VA

Classification: Class I, Type B, IPX0, Continuous Operation

Solicitante:

Applicant/Solicitante

SISMATEC INDÚSTRIA E COMÉRCIO DE EQUIP. HOSPITALARES LTDA.

Rua Omílio Monteiro Soares, 1614 – Vila Fanny

81030-001 – Curitiba – PR

CNPJ: 78.380.987/0001-04

Fabricante:

Manufacturer/Fabricante

SISMATEC INDÚSTRIA E COMÉRCIO DE EQUIP. HOSPITALARES LTDA.

Rua Omílio Monteiro Soares, 1614 – Vila Fanny

81030-001 – Curitiba – PR

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Normas Técnicas:

Standards/Normas

NBR IEC 60601-1:1994 + Amendment 01:1997;

NBR IEC 60601-1-2:2006.

In accordance with the requirements of Ordinance 350, 06th September, 2010 - INMETRO.

Under the Resolution nº 27, 21st de June, 2011 - ANVISA.

Concessão:

Concession/Concesión

License to Use the Mark of the Brazilian System of Conformity Assessment.

Laboratório de Ensaio:

Testing Laboratory/Laboratorio de Ensayo

**Integration and Test Laboratory of the National Institute of Space Research (LIT-INPE);
TÜV Rheinland in Brazil Ltda.**

Nº do Relatório de Ensaio – Data:

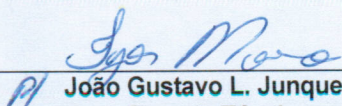
Test Report Number – Date / -

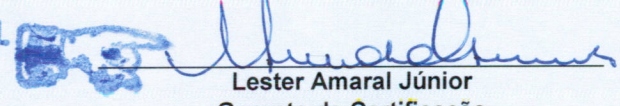
Nº del informe de Ensayo - Fecha

TUVBR22-R03 - 09/04/2010; TUVBR79-R01 - 01/11/2011;

0382-MED - 13/05/2010; 0981-MED - 06/10/2011;

0994-MED - 13/10/2010 e 1085-MED - 27/10/2011.


João Gustavo L. Junqueira
Gerente Técnico
Technical Manager / Gerente Técnico


Lester Amaral Júnior
Gerente de Certificação
Certification Manager / Gerente de Certificación



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Versão do Software avaliado:

Software Version evaluated/ Versión del software evaluado

Not applied

Versão do Manual do usuário e do Projeto do Produto avaliado:

Version of the User Manual and Product Design Rated/ Versión del Manual de usuario y diseño de producto clasificado

**User Manual Multifunctional Surgical Light
Codes 090070 (revision D)**

**User Manual Stand Type Surgical Light
Codes 090013 (revision D)**

Lista de acessórios e partes ensaiadas em conjunto com o produto:

List of accessories and parts tested in conjunction with the product/ Lista de accesorios y piezas de prueba en relación con el producto

Data de Emissão:

Date of issue/Fecha de Otorgamiento

São Paulo, January 03, 2012.

Historic:

29/11/2010 – Initial issuance of the Certificate;

21/11/2011 – Revision 01 – Inclusion of new models and adequacy requirements of Ordinance 350 - INMETRO.