



2024 - AÑO DE LA DEFENSA DE LA VIDA, LA
LIBERTAD Y LA PROPIEDAD

Ministerio de Salud
Secretaría de Calidad en Salud
A.N.M.A.T.

ANEXO II

DECLARACIÓN DE CONFORMIDAD DE MODIFICACIÓN – PM CLASE I- II

Número de revisión: 1365-222#0002

Fecha de Emisión de la Declaración revisión 00-Disposición Autorizante o su reválida:
19/02/2019

Número de PM:

1365-222

Nombre Descriptivo del producto:

Lámpara para Cirugía

Código de identificación y nombre técnico UMDNS:

12-282 Luces, para Cirugía

Clase de Riesgo:

Clase I

Marca de (los) producto(s) médico(s):

MAQUET

Modelos (en caso de clase II y equipos):

PowerLED II range:

PowerLED II 500 & PowerLED II 700

PWDII70SF AIM K3 08

PWDII50DF VP AIM CL XO K4 1416

PWDII50DF VP AIM CL XO K4 1416

PWDII75SFDF AIM CL MHS013 K3 081011

PWDII75SFDF AIM CL MHS013 K4 081011

PWDII75SFDF AIM CL MHS021 K3 081011

PWDII75SFDF AIM CL MHS021 K4 081011
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PWDII70SF VP AIM K3 11
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PWDII75SF VP K3 XHS016 SAX081012
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Composición cuali-cuanti porcentual exacta (si corresponde):

NA

Indicación/es autorizada/s:

La gama Maquet PowerLED II está diseñada para iluminar el cuerpo del paciente durante las operaciones quirúrgicas, de diagnóstico o de tratamiento

Período de vida útil (si corresponde):

10 años

Método de Esterilización (si corresponde):

NA

Forma de presentación:

Unitaria

Condición de uso:

Uso exclusivo a profesionales e instituciones sanitarias

Nombre del fabricante:

MAQUET SAS

Lugar/es de elaboración:

Parc de Limère- Avenue de la Pomme de pin - CS 10008

ARDON - 45074 ORLEANS Cedex 2-FRANCIA

En nombre y representación de la firma AGIMED S.R.L. , el responsable legal y el responsable técnico declaran bajo juramento que los productos médicos enumerados en el presente Anexo, satisfacen los Requisitos Esenciales de Seguridad y Eficacia (R.E.S.E.) previstos por la Disposición ANMAT N° 4306/99, que cumplen y se encuentra a disposición de la Autoridad Sanitaria la documentación técnica que contenga los requerimientos solicitados en los Anexos III.B y III.C del Reglamento Técnico aprobado por Disposición ANMAT N° 2318/02 (TO 2004) y Disposición ANMAT N° 9688/19.

CUMPLIMIENTO DE R.E.S.E. DISPOSICIÓN ANMAT N° 4306/99 Y GESTIÓN DE RIESGO

ENSAYO/VALIDACION/GESTION DE RIESGO	LABORATORI	FECHA
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11.2)EN ISO 15223-1 EN 1041 EN 60825-1 11.3 y 11.4)EN 60601-1 EN 60601-2-41 EN ISO 14971 EN ISO 15223-1 EN 1041 12.1) EN 60601-1 EN 62304 EN ISO 14971 12.2)NA 12.3)EN 60601-1 12.4)NA 12.5)EN 60601-1 EN 60601-1-2 EN ISO 14971 12.6)EN 60601-1 EN 60601-2-41 EN ISO 14971 12.7.1)EN 60601-1 EN 60601-2-41 EN ISO 14971 12.8) NO APLICA 12.9)EN 60601-1 EN 1041 EN 60601-1-6 EN 62366 13.1)EN 60601-1 EN ISO 15223-1 EN 1041 EN 60601-1-6 EN 62366 13.2)EN 60601-1 EN ISO 15223-1 EN 1041 13.3) EN 60601-1 EN ISO 14971 EN ISO 15223-1 EN 1041 13.4 Y 13.5)EN 60601-1 EN ISO 15223-1 EN 1041 13.6)EN 60601-1 EN 60601-2-41 EN ISO 14971 EN ISO 15223-1 EN 1041		
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El responsable legal y su responsable técnico son responsables de la veracidad de la documentación e información presentada y declaran bajo juramento mantener en su establecimiento y a disposición de la autoridad sanitaria la documentación allí declarada y la que establece la Disposición 9688/19, bajo apercibimiento de lo que establece la Ley N° 16.463, el Decreto N° 341/92 y las que correspondan del Código Penal en caso de falsedad.

En caso de inexactitud o falsedad de la información o documentación, la Administración Nacional podrá suspender, cancelar, prohibir la comercialización y solicitar retiro del mercado de lo ya autorizado e iniciar los sumarios que pudieran corresponder.

LUGAR Y FECHA: Argentina, 31 mayo 2024



SCIOLLA Fernando Sergio
Cul 202316190331

Firma y Sello



GOMEZ Leonardo Francisco
CUIL 20257816894

Responsable Técnico
Firma y Sello



Ministerio de Salud
Secretaría de Calidad en Salud
A.N.M.A.T.

La presente DECLARACIÓN DE CONFORMIDAD ha sido emitida de acuerdo con las previsiones de la Disposición ANMAT N° 9688/19, quedando inscripta la modificación en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) a favor de **AGIMED S.R.L.** bajo el número PM **1365-222** en la Ciudad de Buenos Aires a los días 31 mayo 2024

Se autoriza la comercialización del/los producto/s identificados en la presente declaración de conformidad, la cual mantendrá la vigencia que consta en la Declaración inicial revisión 00 o Disposición Autorizante o su reválida.



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Código "N°rev legajo#version" vigente a partir de 07/02/22, reemplaza la anterior codificación.
La validez del presente documento deberá verificarse mediante el código QR.

Tramitada por Expediente N°: 1-0047-3110-001521-24-8



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