

Declaración de Conformidad

Fabricante: Shenzhen Jermei Medical Device Technology Co., Ltd
Room 201,202,4th Bldg XianYuXing Company, 4th Bldg
XianYuXing industrial Zone,Yuhe Road,Gonghe
Community,Shajing Street, Baoan District, Shenzhen,
P.R.China

Representante: Luxus Lebenswelt GmbH
Europeo: Kochstr.1, 47877,Willich Germany

Nombre del Producto: Ultrasonic Nebulizer

Modelos: JM-06801,JM-06801A,JM-06801B,JM-06802

GMDN Code: 12719

Clasificación (MDD, Anexo IX): **Ila, Rule 11**

Procedimiento de Evaluación de la Conformidad: **Annex V and Annex VII**

Por la presente declaramos que los productos mencionados cumplen con la transposición al derecho nacional, las disposiciones de las siguientes Directivas y Normas del Consejo de la CE. Toda la documentación de respaldo se conserva en las instalaciones del fabricante. Somos exclusivamente responsables de esta DoC.

Directivas aplicables generales:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device (MDD 93/42/EEC), Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Normas:

EN ISO 14971: 2012, EN ISO 15223-1:2016, EN 1041:2008, IEC 60601-1:2005,COR1:2006,CORP:2007,AMD1:2012(IEC 60601-1:2012 reprint), EN 13544:2007+A1:2009, IEC 60601-1-11:2015,IEC 60601-1-2:2014, IEC 62304:2006,IEC 60601-1-6:2010,AMD1:2013, IEC 62366-1:2007,AMD1:2014, ISO 10993-5:2009,ISO 10990-10:2010

Organismo Notificado: SGS FIMKO OY
Takomotie 8
00380 HELSINKI

Número de identificación del ON: 0598

Certificado(s) (CE): FI21/07051P0

Fecha de caducidad del certificado: May 24,2024

Inicio del Mercado CE: May 18,2021

Lugar, Fecha de emisión: Shenzhen, October 5,2021

Firma:

Nombre:

Cargo:


Fan B L
Quality Manager

Konformitätserklärung

Hersteller: Shenzhen Jermei Medical Device Technology Co., Ltd
Room 201,202,4th Bldg XianYuXing Company, 4th Bldg
XianYuXing industrial Zone,Yuhe Road,Gonghe
Community,Shajing Street, Baoan District, Shenzhen,
P.R.China

Europäischer Luxus Lebenswelt GmbH
Bevollmächtigter: Kochstr.1, 47877,Willich Germany
Produktname: Ultrasonic Nebulizer
Modelle: JM-06801,JM-06801A,JM-06801B,JM-06802
GMDN Code: 12719
Klassifizierung (MDD, Annex IX): **Ila, Rule 11**
Konformitätsbewertungsverfahren: **Annex V and Annex VII**

Hiermit erklären wir, dass die oben genannten Produkte der Umsetzung in nationales Recht sowie den Bestimmungen der folgenden EG-Richtlinien und Normen entsprechen. Alle unterstützenden Unterlagen werden in den Räumlichkeiten des Herstellers aufbewahrt. Wir tragen die alleinige Verantwortung für diese Konformitätserklärung (DOC).

Allgemein anwendbare Richtlinien:

Medizinprodukterichtlinie: Richtlinie des Rates 93/42/EWG vom 14. Juni 1993 über Medizinprodukte (MDD 93/42/EWG), geändert durch die Richtlinie 2007/47/EG vom 5. September 2007.

Normen:

EN ISO 14971: 2012, EN ISO 15223-1:2016, EN 1041:2008, IEC 60601-1:2005,COR1:2006,CORP:2007,AMD1:2012(IEC 60601-1:2012 reprint), EN 13544:2007+A1:2009, IEC 60601-1-11:2015,IEC 60601-1-2:2014, IEC 62304:2006,IEC 60601-1-6:2010,AMD1:2013, IEC 62366-1:2007,AMD1:2014, ISO 10993-5:2009,ISO 10990-10:2010

Benannte Stelle: SGS FIMKO OY
Takomotie 800380 HELSINKI

Kennnummer der Benannten Stelle: 0598
(EG)Konformitätsbescheinigung(en): FI21/07051P0
Ablaufdatum des Zertifikats: May 24,2024
Beginn der CE-Kennzeichnung: May 18,2021
Ort, Ausstellungsdatum: Shenzhen, October 5,2021
Unterschrift:

Name:

Position:

Fang L.
Quality manager



Declaration of Conformity

Manufacturer: Shenzhen Jermei Medical Device Technology Co., Ltd
Room 201,202,4th Bldg XianYuXing Company, 4th Bldg
XianYuXing industrial Zone,Yuhe Road,Gonghe
Community,Shajing Street, Baoan District, Shenzhen,
P.R.China

European Representative: Luxus Lebenswelt GmbH
Kochstr.1, 47877,Willich Germany

Product Name: Ultrasonic Nebulizer

Models: JM-06801,JM-06801A,JM-06801B,JM-06802

GMDN Code: 12719

Classification (MDD, Annex IX): **Ila, Rule 11**
Conformity Assessment Procedure: **Annex V and Annex VII**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for this DoC.

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device (MDD 93/42/EEC), Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Standards:

EN ISO 14971: 2012, EN ISO 15223-1:2016, EN 1041:2008, IEC 60601-1:2005,COR1:2006,CORP:2007,AMD1:2012(IEC 60601-1:2012 reprint), EN 13544:2007+A1:2009, IEC 60601-1-11:2015,IEC 60601-1-2:2014, IEC 62304:2006,IEC 60601-1-6:2010,AMD1:2013, IEC 62366-1:2007,AMD1:2014, ISO 10993-5:2009,ISO 10990-10:2010

Notified Body: SGS FIMKO OY
Takomotie 8
00380 HELSINKI

NB Identification number: 0598

(EC) Certificate(s): FI21/07051P0

Expire date of the Certificate: May 24,2024

Start of CE Marking: May 18,2021

Place, Date of Issue: Shenzhen, October 5,2021

Signature:

Name:

Position:

JingL
Quality Manager



Déclaration de conformité

Fabricant:: Shenzhen Jermei Medical Device Technology Co., Ltd
Room 201,202,4th Bldg XianYuXing Company, 4th Bldg
XianYuXing industrial Zone,Yuhe Road,Gonghe
Community,Shajing Street, Baoan District, Shenzhen,
P.R.China

Représentant
européen: Luxus Lebenswelt GmbH
Kochstr.1, 47877,Willich Germany

Nom du produit: Ultrasonic Nebulizer

modèles: JM-06801,JM-06801A,JM-06801B,JM-06802

GMDN Code: 12719

Classification (MDD, Annexe IX) :: **Ila, Rule 11**

Procédure d'évaluation de la conformité : **Annex V and Annex VII**

Nous déclarons par la présente que les produits susmentionnés sont conformes aux dispositions transposées en droit national des directives et normes suivantes du Conseil des CE. Tous les documents justificatifs sont conservés dans les locaux du fabricant. Nous assumons l'entière responsabilité de la présente DoC.

Directives généralement applicables :

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device (MDD 93/42/EEC), Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Normes:

EN ISO 14971: 2012, EN ISO 15223-1:2016, EN 1041:2008, IEC 60601-1:2005,COR1:2006,CORP:2007,AMD1:2012(IEC 60601-1:2012 reprint), EN 13544:2007+A1:2009, IEC 60601-1-11:2015,IEC 60601-1-2:2014, IEC 62304:2006,IEC 60601-1-6:2010,AMD1:2013, IEC 62366-1:2007,AMD1:2014, ISO 10993-5:2009,ISO 10990-10:2010

Organisme Notifié: SGS FIMKO OY
Takomotie 8
00380 HELSINKI

Numéro d'identification de l'ON: 0598

Certificat(s) (CE): FI21/07051P0

Début du Marquage CE: May 24,2024

Lieu, Date de délivrance: May 18,2021

Place, Date of Issue: Shenzhen, October 5,2021

Signature:

Nom:

Fonction:


Fang Li
Quality manager

Dichiarazione di Conformità

Produttore: Shenzhen Jermei Medical Device Technology Co., Ltd
Room 201,202,4th Bldg XianYuXing Company, 4th Bldg
XianYuXing industrial Zone,Yuhe Road,Gonghe
Community,Shajing Street, Baoan District, Shenzhen,
P.R.China

Rappresentante: Luxus Lebenswelt GmbH
Europeo: Kochstr.1, 47877,Willich Germany

Nome del Prodotto: Ultrasonic Nebulizer

Modelli: JM-06801,JM-06801A,JM-06801B,JM-06802

Codice GMDN: 12719

Classificazione (MDD, Allegato IX): **Ila, Rule 11**

Procedura di Valutazione della Conformità: **Annex V and Annex VII**

Con la presente dichiariamo che i prodotti sopra menzionati sono conformi al recepimento nel diritto nazionale e alle disposizioni delle seguenti Direttive e Norme del Consiglio CE. Tutta la documentazione di supporto è conservata presso la sede del produttore. Siamo gli unici responsabili della presente Dichiarazione di Conformità.

Direttive generali applicabili:

DIRETTIVA DEL CONSIGLIO 93/42/CEE del 14 giugno 1993 concernente i dispositivi medici (MDD 93/42/CEE), come modificata dalla DIRETTIVA 2007/47/CE del 5 settembre 2007.

Norme:

EN ISO 14971: 2012, EN ISO 15223-1:2016, EN 1041:2008, IEC 60601-1:2005,COR1:2006,CORP:2007,AMD1:2012(IEC 60601-1:2012 reprint), EN 13544:2007+A1:2009, IEC 60601-1-11:2015,IEC 60601-1-2:2014, IEC 62304:2006,IEC 60601-1-6:2010,AMD1:2013, IEC 62366-1:2007,AMD1:2014, ISO 10993-5:2009,ISO 10990-10:2010

Organismo Notificato:

SGS FIMKO OY
Takomotie 8
00380 HELSINKI

Numero di identificazione dell' Organismo Notificato:

0598

Certificato(i) CE:

FI21/07051P0

Data di scadenza del certificato:

May 24,2024

Inizio della Marcatura CE:

May 18,2021

Luogo e Data di Emissione:

Shenzhen, October 5,2021

Firma:

Nome:

Posizione:

Fang Li
Quality Manager

