INSTRUCTIONS FOR USE (IFU)

Dandy / Zima International, Inc. | AUS · EU/EN · EU/ES · EU/FR · EU/DE · EU/IT · UK

MANUFACTURER

Manufacturer	Zima International, Inc. Also DBA Dandy
Address	1320 N. 300 W., Lehi, UT 84043, United States
Contact / Website	www.meetdandy.com
Complaints	complaints@meetdandy.com

DEVICE IDENTITY

Device Identity

Device Family	Sleep-Disordered Breathing Orthosis
GMDN / EMDN Code	47526
Product Code(s)	SLEEPAPD, SLEEPAPH, SLEEPAPPC, SLEEPAPX3
Device Type	Custom-made dental device (CMD) / Patient Matched Medical Device (PMMD)
Sterility	Not supplied sterile
Single-use / Reuse	Reusable
Intended User	Prescriber: Dental professional / dental practice

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AUSTRALIA (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

Australia — Patient Matched Medical Device (PMMD)

GMDN / EMDN	47526
Product Code(s)	SLEEPAPD, SLEEPAPH, SLEEPAPPC, SLEEPAPX3

Manufacturer	**Zima International, Inc. Also DBA Dandy** 1320 N. 300 W., Lehi, UT 84043 United States
Australian Sponsor	**Name: DANDY Labs AUS Pty Ltd** **Company No.:** ABN: 33693955761 **Address:** Tower One - International Towers, Level 46, 100 Barangaroo Avenue, Sydney, New South Wales 2000, Australia

Intended User	Prescriber — Dental professional / dental practice
Device Type	Patient Matched Medical Device (PMMD)
Sterility	Not supplied sterile
Single-use / Reusable	Reusable

1) Intended Purpose (Intended Use)

A Dandy sleep apnea device is a type of dental device used to treat snoring and mild to moderate obstructive sleep apnea. It is also known as a mandibular advancement device or mandibular repositioning device.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Dandy devices are custom-made to fit your patient's mouth and are designed to be as comfortable and unobtrusive as possible.
- Material: PMMA Block or Nylon

PMMA Block

Nylon

3) Contraindications

- Sleep apnea devices may not be appropriate for individuals with severe respiratory conditions, such as severe chronic obstructive pulmonary disease (COPD), severe asthma, or other conditions that the use of positive airway pressure could exacerbate.
- Oral devices, which are used to treat sleep apnea by repositioning the jaw and tongue, may not be suitable for individuals with severe dental issues, such as untreated gum disease or extensive

tooth decay. Similarly, individuals with severe jaw problems or temporomandibular joint (TMJ) disorders may require careful evaluation to determine if an oral appliance is appropriate.

4) Warnings / Precautions / Potential Risks

⚠ WARNING

It is common for patients to experience some initial discomfort or soreness when the appliance is first placed or adjusted. This discomfort usually subsides as the patient adapts to the device.

⚠ CAUTION

N/A

5) Cleaning and Care

Directions for Use

To ensure proper use of the devices, follow these steps:

- Before inserting the sleep apnea device, brush and floss the teeth and rinse the mouth with water to ensure good oral hygiene and prevent any food particles from getting trapped under the device.
- The appliance is crafted to cover the upper and lower teeth and stays secure through adaptable metallic connectors. You may engage the device by means of adjustable lugs or by the Herbst® mechanism, which is a rod and tube assembly that orients the jaws in a predetermined relationship. Place the upper piece of the appliance in the patient's mouth and have the patient bite down gently to position it properly.
- The Herbst® is a one-piece construction held together by two adjustment mechanisms on the buccal or outer area of the upper and lower appliances. The adjustment mechanisms are designed for the doctor to advance the mandible to the desired position incrementally. Dorsal is a two-piece design with separate upper and lower acrylic portions that, when engaged, propel the mandible into a protrusive position via acrylic fins built in the lower acrylic portion.
- The Dorsal is an adjustable design utilizing advancement; once the upper piece is in place, insert the lower piece of the device, and then adjust the metal connectors to hold the lower jaw in a slightly advanced position. Finding the most comfortable and effective position may require some trial and error.
- The patient should breathe through their nose and ensure that the appliance is properly seated and comfortable. It may take some time to adjust to the feeling of the appliance in the mouth, but most patients find that they can sleep comfortably with it in place.
- The patient is advised to use the device according to the guidelines provided by your practice, which may encompass detailed instructions regarding the daily duration of wear and the appropriate times for removal.

Cleaning instructions

- Dandy recommends cleaning your sleep apnea device daily before and after every use. Immediately after removal, use warm water (not to exceed 45°C/113°F) and soap to remove remaining saliva and debris from the device. The manufacturer advises against immersing the device in solutions, which could lead to delamination.

6) Storage

Use a case specifically designed for dental devices to protect them from contamination and damage. The case should have good airflow to prevent moisture buildup.

7) Expected Life / Service

Sleep apnea mouth appliances (oral appliances) typically last 2 to 5 years, but this duration can vary depending on the design and care. Signs indicating the need for replacement include a poor fit, wear, or reduced effectiveness. Therefore, regular dental check-ups are crucial to monitor their condition and ensure they remain functional.

8) Incident / Complaint Reporting

Report suspected serious incidents associated with this device to:

- The Manufacturer and/or Dandy Australia entity using the contacts above, and
- Therapeutic Goods Administration (TGA)

In Australia, serious incidents involving medical devices must be reported to the TGA in accordance with the Therapeutic Goods Act 1989.

> ***INFO***
> *For full contact details of the local Authorized Representative, refer to: Authorized Representatives — end of this document.*

9) Disposal

To dispose of a sleep apnea oral appliance, you should primarily consult with your dental specialist or use local e-waste/recycling facilities. Do not dispose of it with regular household trash unless directed by local regulations.

EUROPEAN UNION (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

European Union — Custom-Made Device (CMD)

GMDN / EMDN	Q030102 - ANTISNORING AND OBSTRUCTIVE SLEEP APNOEA DEVICES
Product Code(s)	SLEEPAPD, SLEEPAPH, SLEEPAPPC, SLEEPAPX3

Manufacturer	**Zima International, Inc. Also DBA Dandy** 1320 N. 300 W., Lehi, UT 84043 United States
EU authorized representative (EURP)	**Name:** Dandy Labs Europe **Company No.:** Registration No.: 989857065 **Address:** 3, boulevard de Sebastopol, 75001 Paris, France

Intended User	Prescriber — Dental professional / dental practice
Device Type	Custom-made dental device (CMD)
Sterility	Not supplied sterile
Single-use / Reusable	Reusable

1) Intended Purpose (Intended Use)

A Dandy sleep apnea device is a type of dental device used to treat snoring and mild to moderate obstructive sleep apnea. It is also known as a mandibular advancement device or mandibular repositioning device.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Dandy devices are custom-made to fit your patient's mouth and are designed to be as comfortable and unobtrusive as possible.
- Material: PMMA Block or Nylon

PMMA Block

Nylon

3) Contraindications

- Sleep apnea devices may not be appropriate for individuals with severe respiratory conditions, such as severe chronic obstructive pulmonary disease (COPD), severe asthma, or other conditions that the use of positive airway pressure could exacerbate.
- Oral devices, which are used to treat sleep apnea by repositioning the jaw and tongue, may not be suitable for individuals with severe dental issues, such as untreated gum disease or extensive

tooth decay. Similarly, individuals with severe jaw problems or temporomandibular joint (TMJ) disorders may require careful evaluation to determine if an oral appliance is appropriate.

4) Warnings / Precautions / Potential Risks

⚠ WARNING

It is common for patients to experience some initial discomfort or soreness when the appliance is first placed or adjusted. This discomfort usually subsides as the patient adapts to the device.

⚠ CAUTION

n/a

5) Cleaning and Care

Directions for Use

To ensure proper use of the devices, follow these steps:

- Before inserting the sleep apnea device, brush and floss the teeth and rinse the mouth with water to ensure good oral hygiene and prevent any food particles from getting trapped under the device.
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- The Dorsal is an adjustable design utilizing advancement; once the upper piece is in place, insert the lower piece of the device, and then adjust the metal connectors to hold the lower jaw in a slightly advanced position. Finding the most comfortable and effective position may require some trial and error.
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- The patient is advised to use the device according to the guidelines provided by your practice, which may encompass detailed instructions regarding the daily duration of wear and the appropriate times for removal.

Cleaning instructions

- Dandy recommends cleaning your sleep apnea device daily before and after every use. Immediately after removal, use warm water (not to exceed 45°C/113°F) and soap to remove remaining saliva and debris from the device. The manufacturer advises against immersing the device in solutions, which could lead to delamination.

6) Storage

Use a case specifically designed for dental devices to protect them from contamination and damage. The case should have good airflow to prevent moisture buildup.

7) Expected Life / Service

Sleep apnea mouth appliances (oral appliances) typically last 2 to 5 years, but this duration can vary depending on the design and care. Signs indicating the need for replacement include a poor fit, wear, or reduced effectiveness. Therefore, regular dental check-ups are crucial to monitor their condition and ensure they remain functional.

8) Incident / Complaint Reporting

Report suspected serious incidents associated with this device to:

- The Manufacturer and/or Dandy EU entity using the contacts above, and corresponding local requirements
- The Competent Authority of your Member State, in accordance with Regulation (EU) 2017/745 (MDR).

Competent Authorities:

- France: Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
- Germany : Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (BfArM)
- Italy : Ministero della Salute / Istituto Superiore di Sanità (ISS)
- Spain: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
- Netherlands: Inspectie Gezondheidszorg en Jeugd (IGJ)
- Austria: Bundesamt für Sicherheit im Gesundheitswesen (BASG)
- Sweden: Läkemedelsverket
- Denmark: Lægemiddelstyrelsen
- Portugal: Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED)

> ***INFO***
> *For full contact details of the local Authorized Representative, refer to: Authorized Representatives — end of this document.*

9) Disposal

To dispose of a sleep apnea oral appliance, you should primarily consult with your dental specialist or use local e-waste/recycling facilities. Do not dispose of it with regular household trash unless directed by local regulations.

UNIÓN EUROPEA (ESPAÑOL)

INSTRUCCIONES DE USO (IFU)

Unión Europea — Producto Sanitario a Medida (CMD)

GMDN / EMDN	Q030102 - DISPOSITIVOS ANTIRONQUIDOS Y PARA EL TRATAMIENTO DE LA APNEA OBSTRUCTIVA DEL SUEÑO
Código(s) del producto	SLEEPAPD, SLEEPAPH, SLEEPAPPC, SLEEPAPX3

Fabricante	**Zima International, Inc. Also DBA Dandy** 1320 N. 300 W., Lehi, UT 84043 United States
Persona Responsable de la UE (EURP)	**Nombre:** Dandy Labs Europa **N° empresa:** Número de empresa: 989857065 **Domicilio:** 3, boulevard de Sebastopol, 75001 París, Francia

Usuario previsto	Prescriptor: profesional dental / consulta dental
Tipo de dispositivo	Dispositivo dental a medida (CMD)
Esterilidad	No se suministra estéril
De un solo uso / Reutilizable	Reutilizable

1) Finalidad prevista (uso previsto)

Un dispositivo Dandy para la apnea del sueño es un dispositivo dental utilizado para tratar los ronquidos y la apnea obstructiva del sueño leve a moderada. También se conoce como dispositivo de avance mandibular o dispositivo de reposicionamiento mandibular.

2) Descripción del dispositivo / Especificaciones clave

- Dispositivo a medida y específico para el paciente, fabricado según la prescripción del profesional dental y los datos digitales de entrada.
- Configuración: Los dispositivos Dandy se fabrican a medida para adaptarse a la boca del paciente y están diseñados para ser lo más cómodos y discretos posible.
- Material: Bloque de PMMA o Nylon

Bloque de PMMA

Nylon

3) Contraindicaciones

Los dispositivos para la apnea del sueño pueden no ser adecuados para personas con afecciones respiratorias graves, como enfermedad pulmonar obstructiva crónica (EPOC) grave, asma grave u otras afecciones que podrían verse agravadas por la presión positiva en las vías respiratorias.

Los dispositivos orales utilizados para tratar la apnea del sueño mediante el reposicionamiento de la mandíbula y la lengua pueden no ser adecuados para personas con problemas dentales graves, como

enfermedad periodontal sin tratar o caries extensas. Del mismo modo, las personas con problemas graves de mandíbula o trastornos de la articulación temporomandibular (ATM) pueden requerir una evaluación cuidadosa para determinar si un aparato oral es adecuado.

4) Advertencias / Precauciones / Riesgos potenciales

⚠ ADVERTENCIAS

Es habitual que los pacientes experimenten molestias o dolor inicial cuando el aparato se coloca o se ajusta por primera vez. Esta molestia suele desaparecer a medida que el paciente se adapta al dispositivo.

⚠ PRECAUCIONES

NA

5) Limpieza y cuidado

Instrucciones de uso

Para garantizar el uso correcto de los dispositivos, siga estos pasos:

- Antes de insertar el dispositivo para la apnea del sueño, cepíllese los dientes, use hilo dental y enjuáguese la boca con agua para mantener una buena higiene bucal y evitar que queden partículas de comida atrapadas debajo del dispositivo.
- El aparato está diseñado para cubrir los dientes superiores e inferiores y mantenerse en su sitio mediante conectores metálicos ajustables. El dispositivo puede activarse mediante elementos de ajuste regulables o mediante el mecanismo Herbst ® , un conjunto de varilla y tubo que orienta los maxilares en una relación predeterminada. Coloque la parte superior del aparato en la boca del paciente y pídale que muerda suavemente para posicionarla correctamente.
- El Herbst ® es una estructura de una sola pieza mantenida por dos mecanismos de ajuste situados en la zona bucal o externa de los aparatos superior e inferior. Los mecanismos de ajuste están diseñados para que el facultativo avance la mandíbula de forma incremental hasta la posición deseada. El Dorsal es un diseño de dos piezas con porciones acrílicas superior e inferior separadas que, al acoplarse, llevan la mandíbula a una posición protrusiva mediante aletas acrílicas incorporadas en la porción inferior.
- El dorsal es un diseño ajustable que utiliza avance; una vez que la pieza superior esté en su lugar, inserte la pieza inferior del dispositivo y luego ajuste los conectores metálicos para mantener la mordaza inferior en una posición ligeramente avanzada. Encontrar la posición más cómoda y eficaz puede requerir cierto ensayo y error.
- El paciente debe respirar por la nariz y asegurarse de que el aparato esté bien asentado y cómodo. Puede requerirse un tiempo de adaptación a la sensación del aparato en la boca, pero la mayoría de los pacientes comprueban que pueden dormir cómodamente con él colocado.
- Se recomienda al paciente que utilice el dispositivo de acuerdo con las directrices proporcionadas por su clínica, que pueden incluir instrucciones detalladas sobre la duración diaria de uso y los momentos adecuados para retirarlo.

Instrucciones de limpieza

- Dandy recomienda limpiar a diario el dispositivo para la apnea del sueño, antes y después de cada uso. Inmediatamente después de retirarlo, utilice agua tibia (sin superar los 45 °C/113 °F) y jabón para eliminar los restos de saliva y residuos del dispositivo. El fabricante aconseja no sumergir el dispositivo en soluciones, lo que podría provocar la delaminación.

6) Almacenamiento

Utilice un estuche diseñado específicamente para dispositivos dentales para protegerlos de la contaminación y los daños. El estuche debe tener un buen flujo de aire para evitar la acumulación de humedad.

7) Vida esperada / Servicio

Los dispositivos orales para la apnea del sueño suelen durar entre 2 y 5 años, aunque este periodo puede variar en función del diseño y de los cuidados. Entre los signos que indican la necesidad de sustitución se incluyen un mal ajuste, el desgaste o una menor eficacia. Por tanto, las revisiones dentales periódicas son fundamentales para controlar su estado y garantizar que sigan siendo funcionales.

8) Notificación de incidentes / Reclamaciones

Comunique cualquier sospecha de incidente grave relacionado con este producto a:

- El fabricante y/o la entidad de Dandy en la UE utilizando los datos de contacto indicados anteriormente, así como conforme a los requisitos locales aplicables
- La Autoridad Competente de su Estado Miembro, de conformidad con el Reglamento (UE) 2017/745 (MDR).

Autoridades competentes:

- France: Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
- Germany : Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (BfArM)
- Italy : Ministero della Salute / Istituto Superiore di Sanità (ISS)
- Spain: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
- Netherlands: Inspectie Gezondheidszorg en Jeugd (IGJ)
- Austria: Bundesamt für Sicherheit im Gesundheitswesen (BASG)
- Sweden: Läkemedelsverket
- Denmark: Lægemiddelstyrelsen
- Portugal: Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED)

INFO

Para los datos completos de contacto del Representante Autorizado local, consulte: Representantes Autorizados — fin de este documento.

9) Eliminación

Para desechar un aparato oral para la apnea del sueño, debe consultar en primer lugar con su especialista dental o recurrir a instalaciones locales de reciclaje o eliminación de residuos electrónicos, si procede. No lo deseche con la basura doméstica habitual a menos que así lo indique la normativa local.

UNION EUROPÉENNE (FRANÇAIS)

INSTRUCTIONS D'UTILISATION (IFU)

Union Européenne — Dispositif sur Mesure (CMD)

GMDN / EMDN	Q030102 - APPAREILS ANTIRONFLEMENT ET APNÉE OBSTRUCTIVE DU SOMMEIL
Code(s) produit	SLEEPAPD, SLEEPAPH, SLEEPAPPC, SLEEPAPX3

Fabricant	Zima International, Inc. Also DBA Dandy 1320 N. 300 W., Lehi, UT 84043 United States
Personne Responsable de l'UE (EURP)	Nom : Dandy Labs Europe N° d'enregistrement: Numéro d'enregistrement: 989857065 Adresse : 3, boulevard de Sebastopol, 75001 Paris, France

Utilisateur prévu	Prescripteur : professionnel dentaire/cabinet dentaire
Type de dispositif	Dispositif dentaire sur mesure (DMC)
Stérilité	Non fourni stérile
Usage unique / Réutilisable	Réutilisable

1) Usage prévu (utilisation prévue)

Un dispositif d'apnée du sommeil Dandy est un type de dispositif dentaire utilisé pour traiter le ronflement et l'apnée obstructive légère à modérée du sommeil. Il est également appelé dispositif d'avancement mandibulaire ou dispositif de repositionnement mandibulaire.

2) Description du dispositif / Caractéristiques principales

- Dispositif sur mesure, spécifique au patient, fabriqué selon les prescriptions des professionnels dentaires et les données d'entrée numériques.
- Paramétrage : Les appareils Dandy sont conçus sur mesure pour s'adapter à la bouche de votre patient et sont conçus pour être aussi confortables et discrets que possible .
- Matériel : Bloc PMMA ou Nylon

Bloc PMMA

Nylon

3) Contre-indications

- Les appareils destinés au traitement de l'apnée du sommeil peuvent ne pas convenir aux personnes souffrant de troubles respiratoires graves, tels qu'une bronchopneumopathie

chronique obstructive (BPCO) sévère, un asthme sévère ou d'autres affections que l'utilisation d'une ventilation en pression positive pourrait aggraver.

- Les appareils buccodentaires, utilisés pour traiter l'apnée du sommeil en repositionnant la mâchoire et la langue, peuvent ne pas convenir aux personnes souffrant de problèmes dentaires graves, tels qu'une maladie des gencives non traitée ou des caries importantes. De même, les personnes souffrant de troubles maxillaires graves ou de troubles de l'articulation temporo-mandibulaire (ATM) peuvent nécessiter un examen approfondi afin de déterminer si un appareil buccodentaire est indiqué.

4) Avertissements / Précautions / Risques potentiels

⚠ AVERTISSEMENTS

Il est fréquent que les patients ressentent une gêne initiale ou une douleur lors de la première mise en place ou du réglage de l'appareil. Cette gêne disparaît généralement au fur et à mesure que le patient s'adapte à l'appareil.

⚠ PRÉCAUTIONS

n/a

5) Nettoyage et entretien

et entretien (Instructions relatives aux soins aux patients — selon les directives du professionnel des soins dentaires)

Mode d'emploi

- Pour garantir une utilisation correcte des dispositifs, suivre les étapes suivantes :
- Avant de mettre en place l'appareil contre l'apnée du sommeil, se brosser les dents, passer du fil dentaire et se rincer la bouche à l'eau afin de garantir une bonne hygiène bucco-dentaire et d'éviter que des résidus alimentaires ne restent coincés sous l'appareil.
- Cet appareil est conçu pour recouvrir les dents du haut et du bas et tient bien en place grâce à des attaches métalliques ajustables. Vous pouvez actionner l'appareil à l'aide de pattes réglables ou du mécanisme Herbst ® , qui consiste en un ensemble de tiges et de tubes permettant d'orienter les mâchoires selon une position prédéterminée. Placer la partie supérieure de l'appareil dans la bouche du patient et lui demander de mordre doucement pour la mettre correctement en place.
- Le Herbst ® est une construction monobloc maintenue ensemble par deux mécanismes de réglage sur la zone buccale ou externe des appareils supérieur et inférieur. Les mécanismes de réglage sont conçus pour que le médecin fasse avancer la mandibule progressivement jusqu'à la position souhaitée. Le modèle Dorsal est composé de deux parties distinctes, une partie supérieure et une partie inférieure en acrylique, qui, une fois emboîtées, propulsent la mandibule en position d'avancée grâce à des ailettes intégrées à la partie inférieure en acrylique.
- Le modèle Dorsal est composé de deux parties distinctes, une partie supérieure et une partie inférieure en acrylique, qui, une fois emboîtées, propulsent la mandibule en position d'avancée grâce à des ailettes intégrées à la partie inférieure en acrylique. Trouver la position la plus confortable et la plus efficace peut nécessiter quelques essais et erreurs.
- Le patient doit respirer par le nez et s'assurer que l'appareil est correctement installé et confortable. Il faudra peut-être un certain temps pour s'habituer à la sensation que procure l'appareil dans la bouche, mais la plupart des patients constatent qu'ils peuvent dormir confortablement avec.
- Il est recommandé au patient d'utiliser l'appareil conformément aux consignes fournies par votre cabinet, qui peuvent inclure des instructions détaillées concernant la durée quotidienne de port et les moments appropriés pour le retirer.

Instructions de nettoyage

- Dandy recommande de nettoyer votre appareil contre l'apnée du sommeil tous les jours, avant et après chaque utilisation. Immédiatement après le retrait, utiliser de l'eau tiède (ne dépassant pas 45°C/113°F) et du savon pour éliminer les résidus de salive et de débris de l'appareil. Le fabricant déconseille de plonger l'appareil dans des solutions, car cela pourrait entraîner un décollement.

6) Stockage

Utilisez un boîtier spécialement conçu pour les appareils dentaires afin de les protéger contre toute contamination et tout dommage. Le boîtier doit avoir un bon flux d'air pour éviter l'accumulation d'humidité.

7) Durée de vie / Service attendu

Les appareils buccodentaires contre l'apnée du sommeil ont généralement une durée de vie de 2 à 5 ans, mais cette durée peut varier en fonction de leur conception et de l'entretien qui en est fait. Parmi les signes indiquant qu'il faut remplacer le produit, on peut citer un mauvais ajustement, l'usure ou une efficacité réduite. Par conséquent, des examens dentaires réguliers sont essentiels pour surveiller leur état et s'assurer qu'ils restent fonctionnels.

8) Signalement des incidents / Réclamations

Signaler tout incident grave suspecté lié à cet appareil :

- Au fabricant et/ou à l'entité Dandy EU en utilisant les coordonnées indiquées ci-dessus, et conformément aux exigences locales aplicables
- L'autorité compétente de votre État membre, conformément au Règlement (UE) 2017/745 (MDR).

Competent Authorities:

- France: Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
- Germany : Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (BfArM)
- Italy : Ministero della Salute / Istituto Superiore di Sanità (ISS)
- Spain: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
- Netherlands: Inspectie Gezondheidszorg en Jeugd (IGJ)
- Austria: Bundesamt für Sicherheit im Gesundheitswesen (BASG)
- Sweden: Läkemedelsverket
- Denmark: Lægemiddelstyrelsen
- Portugal: Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED)

INFO
Pour obtenir les coordonnées complètes du représentant autorisé local, veuillez consulter la section : Représentants autorisés — à la fin du document.

9) Élimination

Pour vous débarrasser d'un appareil buccodentaire contre l'apnée du sommeil, commencer par consulter votre dentiste ou rendez-vous dans un centre local de collecte des déchets électroniques ou de

recyclage. Ne pas les jeter avec les ordures ménagères habituelles, sauf indication contraire de la réglementation locale.

EUROPÄISCHE UNION (DEUTSCH)

GEBRAUCHSANWEISUNG (IFU)

EU-SONDERANFERTIGUNG (CMD – Sonderanfertigung)

GMDN / EMDN	Q030102 – SYSTEME ZUR BEHANDLUNG VON SCHNARCHEN UND OBSTRUKTIVER SCHLAFAPNOE
Produktcode(s)	SLEEPAPD, SLEEPAPH, SLEEPAPPC, SLEEPAPX3

Hersteller	**Zima International, Inc. auch bekannt als Dandy** 1320 N. 300 W., Lehi, UT 84043 Vereinigte Staaten
Bevollmächtigter in der EU (EURP):	**Name = Dandy Labs Europe** Unternehmensnummer = 989857065 Eingetragene Anschrift = 3, boulevard de Sebastopol, 75001 Paris

Vorgesehener Anwender	Verschreibende(r) Zahnarzt/Zahnarztpraxis
Produkttyp	Zahntechnische Sonderanfertigung (CMD)
Sterilität	Wird nicht steril geliefert
Einmalprodukt/wiederverwendbar:	Wiederverwendbar

1) Zweckbestimmung (Verwendungszweck)

Ein Schlafapnoe-Gerät von Dandy ist ein zahnmedizinisches Produkt, das zur Behandlung von Schnarchen und leichter bis mittelschwerer obstruktiver Schlafapnoe eingesetzt wird. Es ist auch als Unterkieferprotrusionsschiene oder Unterkiefer-Repositionierungsgerät bekannt.

2) Produktbeschreibung / Hauptspezifikationen

- Maßgefertigte, patientenspezifische Sonderanfertigung, hergestellt nach zahnärztlicher Verordnung und digitalen Eingabedaten.
- Konfiguration: Die Apparaturen von Dandy werden individuell an den Mund Ihres Patienten angepasst und sind so konzipiert, dass sie so komfortabel und unauffällig wie möglich sind.
- Material: PMMA-Block of Nylon

PMMA-Block
Nylon

3) Kontraindikationen

- Schlafapnoe-Geräte sind möglicherweise nicht geeignet für Personen mit schweren Atemwegserkrankungen, wie schwerer chronisch obstruktiver Lungenerkrankung (COPD),

schwerem Asthma oder anderen Erkrankungen, die sich durch die Anwendung von positivem Atemwegsdruck verschlimmern könnten.

- Intraorale Geräte, die zur Behandlung von Schlafapnoe durch die Neupositionierung von Kiefer und Zunge eingesetzt werden, sind möglicherweise nicht für Personen mit schweren dentalen Problemen wie unbehandelten Zahnfleischerkrankungen oder fortgeschrittenem Kariesbefall geeignet. Ebenso erfordern Personen mit schweren Kieferproblemen oder Erkrankungen des Kiefergelenks (CMD) eine sorgfältige Abklärung, um festzustellen, ob ein intraorales Gerät geeignet ist.

4) Warnhinweise / Vorsichtsmaßnahmen / Potenzielle Risiken

⚠ WARNHINWEISE

Es ist völlig normal, dass Patienten beim ersten Einsetzen oder nach dem Einstellen des Produkts anfänglich leichte Missempfindungen oder Druckschmerzen verspüren. Diese Beschwerden klingen in der Regel ab, sobald sich der Patient an das Produkt gewöhnt hat.

⚠ VORSICHTSMASSNAHMEN

NA

5) Reinigung und Pflege

Gebrauchsanleitung

- Um die korrekte Anwendung der Apparaturen zu gewährleisten, befolgen Sie diese Schritte:
  - Vor dem Einsetzen des Schlafapnoe-Geräts Zähne putzen, Zahnseide verwenden und den Mund mit Wasser ausspülen, um eine gute Mundhygiene zu gewährleisten und zu verhindern, dass Speisereste unter dem Produkt eingeschlossen werden.
  - Die Apparatur ist so gestaltet, dass sie die Zähne des Ober- und Unterkiefers umschließt, und behält ihren sicheren Sitz durch verstellbare metallische Verbindungselemente. Die Aktivierung der Apparatur erfolgt entweder über verstellbare Aktivierungsstege oder über das Herbst®-Scharnier – ein Teleskopstangen-System, das die Kiefer in einer vordefinierten Position zueinander ausrichtet. Setzen Sie das Oberkieferteil der Apparatur in den Mund des Patienten ein und lassen Sie den Patienten leicht zubeißen, um es korrekt zu positionieren.
  - Das Herbst®-System ist eine einteilige Konstruktion, die durch zwei Einstellmechanismen im bukkalen oder äußeren Bereich der Ober- und Unterkiefer-Apparaturen zusammengehalten wird. Die Einstellmechanismen sind so konzipiert, dass der Arzt den Unterkiefer schrittweise in die gewünschte Position vorschieben kann. Das Dorsal-System ist eine zweiteilige Konstruktion mit separaten Ober- und Unterkiefersegmenten aus Acrylat, die den Unterkiefer bei Kieferschluss über integrierte Acrylat-Führungsklingen in eine protrudierte Position vorverlagern.
  - Das Dorsal-System ist eine einstellbare Konstruktion, die auf einer Vorverlagerung basiert; sobald das Oberkieferteil eingesetzt ist, bringen Sie das Unterkieferteil der Apparatur ein und justieren anschließend die metallischen Verbindungselemente, um den Unterkiefer in einer leicht vorverlagerten Position zu halten. Die bequemste und effektivste Position zu finden, kann einige Versuche und Probieren erfordern.
  - Der Patient sollte durch die Nase atmen und sicherstellen, dass die Apparatur korrekt sitzt und bequem ist. Es kann einige Zeit dauern, sich an das Gefühl der Apparatur im Mund zu gewöhnen, aber die meisten Patienten stellen fest, dass sie mit eingesetztem Produkt komfortabel schlafen können.
  - Dem Patienten wird empfohlen, das Produkt gemäß den Richtlinien Ihrer Praxis anzuwenden; diese können detaillierte Anweisungen zur täglichen Tragedauer und zu den geeigneten Zeitpunkten für das Herausnehmen umfassen.

Reinigungsanleitung

- Dandy empfiehlt, Ihr Schlafapnoe-Gerät täglich vor und nach jedem Gebrauch zu reinigen. Verwenden Sie direkt nach dem Herausnehmen warmes Wasser (nicht über 45 °C / 113 °F) und Seife, um verbleibenden Speichel und Rückstände vom Produkt zu entfernen. Der

Hersteller rät davon ab, das Produkt in Flüssigkeiten einzutauchen, da dies zu einer Delamination (Schichtablösung) führen kann.

6) Lagerung

Verwenden Sie eine speziell für zahnmedizinische Produkte entwickelte Box, um diese vor Verunreinigungen und Beschädigungen zu schützen. Die Box sollte eine gute Luftzirkulation aufweisen, um einen Feuchtigkeitsstau zu verhindern.

7) Erwartete Lebensdauer / Zeit der Benutzung

Intraorale Schlafapnoe-Apparaturen (Protrusionsschienen) haben in der Regel eine Lebensdauer von 2 bis 5 Jahren, wobei diese Spanne je nach Konstruktion und Pflege variieren kann. Anzeichen, die auf die Notwendigkeit eines Austauschs hinweisen, sind eine mangelhafte Passform, Verschleiß oder eine nachlassende Wirksamkeit. Daher sind regelmäßige zahnärztliche Kontrolluntersuchungen unerlässlich, um den Zustand des Produkts zu überwachen und dessen Funktionstüchtigkeit zu gewährleisten.

8) Meldung von Vorfällen / Beschwerden

Melden Sie vermutete schwerwiegende Vorkommnisse in Verbindung mit diesem Produkt:

- dem Hersteller und/oder der Dandy EU-Niederlassung unter Verwendung der oben genannten Kontaktdaten und der entsprechenden lokalen Anforderungen
- Die zuständige Behörde Ihres Mitgliedstaats gemäß Verordnung (EU) 2017/745 (MDR).

Competent Authorities:

- France: Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
- Germany : Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (BfArM)
- Italy : Ministero della Salute / Istituto Superiore di Sanità (ISS)
- Spain: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
- Netherlands: Inspectie Gezondheidszorg en Jeugd (IGJ)
- Austria: Bundesamt für Sicherheit im Gesundheitswesen (BASG)
- Sweden: Läkemedelsverket
- Denmark: Lægemiddelstyrelsen
- Portugal: Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED)

INFORMATION
Die vollständigen Kontaktdaten des lokalen Bevollmächtigten finden Sie unter „Bevollmächtigte Vertrete am Ende des Dokuments.

9) Entsorgung

Zur Entsorgung einer intraoralen Schlafapnoe-Apparatur sollten Sie sich in erster Linie an Ihren Zahnarzt wenden oder lokale Sammelstellen für Elektronikschrott/Recycling nutzen. Entsorgen Sie das Produkt nicht über den normalen Hausmüll, es sei denn, die örtlichen Vorschriften sehen dies ausdrücklich vor.

UNIONE EUROPEA (ITALIANO)

ISTRUZIONI PER L'USO (IFU)

DISPOSITIVO PERSONALIZZATO UE (CMD = Dispositivo personalizzato)

GMDN / EMDN	Q030102 – DISPOSITIVI ANTIRUSSAMENTO E PER APNEA OSTRUTTIVA DEL SONNO
Codice(i) prodotto	SLEEPAPD, SLEEPAPH

Produttore	**Zima International, Inc. Also DBA Dandy** 1320 N. 300 W., Lehi, UT 84043 Stati Uniti
Responsabile per l'UE (EURP):	**Nome =** Dandy Labs Europe **Codice azienda =** 989857065 **Sede legale =** 3, boulevard de Sebastopol, 75001 Parigi

Utente previsto	medico odontoiatra prescrittore / studio dentistico
Tipo di dispositivo	dispositivo odontoiatrico personalizzato (CMD)
Sterilità	non fornito sterile
Monouso / Riutilizzabile	Riutilizzabile

1) Destinazione d'uso (uso previsto)

Un dispositivo per apnea notturna Dandy è un tipo di dispositivo dentale utilizzato per il trattamento del russamento e dell'apnea ostruttiva da lieve a moderata. È noto anche come dispositivo di avanzamento mandibolare o dispositivo di riposizionamento mandibolare.

2) Descrizione del dispositivo / Specifiche principali

- Dispositivo personalizzato, specifico per il paziente, prodotto in base alla prescrizione dell'odontoiatra e ai dati di input digitali.
- Configurazione: I dispositivi Dandy sono realizzati su misura per adattarsi alla bocca del paziente e sono progettati per essere il più confortevoli e discreti possibile.
- Materiale: blocco di PMMA o Nylon

Blocco di PMMA

Nylon

3) Controindicazioni

- I dispositivi per apnea notturna possono non essere indicati per le persone con gravi condizioni respiratorie, come la broncopneumopatia cronica ostruttiva (BPCO), asma grave o altre condizioni che l'uso della pressione positiva delle vie respiratorie potrebbe esacerbare.
- I dispositivi orali, utilizzati per trattare l'apnea notturna riposizionando la mandibola e la lingua, possono non essere adatti a soggetti con gravi problemi dentali, come malattie gengivali non trattate o carie dentali estese. Allo stesso modo, i soggetti con gravi problemi alla mandibola o disturbi dell'articolazione temporomandibolare (ATM) possono richiedere un'attenta valutazione per determinare se un apparecchio orale è appropriato.

4) Avvertenze / Precauzioni / Rischi potenziali

⚠ AVVERTENZE
È normale che i pazienti provino disagio o dolore iniziale quando l'apparecchio viene posizionato o regolato per la prima volta. Questo fastidio di solito diminuisce man mano che il paziente si adatta al dispositivo.

⚠ PRECAUZIONI
na

5) Pulizia e cura

Istruzioni per l'uso

- Per garantire un uso corretto dei dispositivi, attenersi alla procedura seguente:
  - Prima di inserire il dispositivo per apnea notturna, lavare i denti e passare il filo interdentale e risciacquare la bocca con acqua per garantire una buona igiene orale ed evitare che eventuali particelle di cibo rimangano intrappolate sotto il dispositivo.
  - L'apparecchio è realizzato per coprire i denti superiori e inferiori e rimane fisso grazie a connettori metallici adattabili. È possibile inserire il dispositivo mediante alette regolabili o tramite il meccanismo Herbst®, un gruppo con barra e tubo che orienta le mandibole secondo una relazione predeterminata. Posizionare il componente superiore dell'apparecchio nella bocca del paziente e chiedere al paziente di mordere delicatamente per posizionarlo correttamente.
  - Il dispositivo Herbst® è una struttura monocomponente tenuta insieme da due meccanismi di regolazione sulla zona buccale o esterna degli apparecchi superiori e inferiori. I meccanismi di regolazione sono progettati per consentire al medico di portare la mandibola nella posizione desiderata in modo incrementale. Il meccanismo Dorsal include due componenti con porzioni acriliche superiori e inferiori separate che, quando inserite, spingono la mandibola in una posizione protratta attraverso alette in acrilico costruite nella porzione acrilica inferiore.
  - Il meccanismo Dorsal è regolabile e sfrutta l'avanzamento; una volta posizionato il componente superiore, inserire il componente inferiore del dispositivo, quindi regolare i connettori metallici per tenere la mandibola inferiore in posizione leggermente avanzata. Per trovare la posizione più comoda ed efficace potrebbe essere necessario fare alcune prove.
  - Il paziente deve respirare attraverso il naso e assicurarsi che l'apparecchio sia posizionato in modo corretto e confortevole. Può essere necessario un po' di tempo per adattarsi alla sensazione dell'apparecchio in bocca, ma la maggior parte dei pazienti scopre che è possibile dormire comodamente con l'apparecchio applicato.
  - Si consiglia al paziente di utilizzare il dispositivo secondo le linee guida fornite dall'ambulatorio, che possono comprendere istruzioni dettagliate sulla frequenza di utilizzo giornaliera e sui tempi appropriati per la rimozione.

Istruzioni per la pulizia

- Dandy consiglia di pulire il dispositivo per apnea notturna ogni giorno prima e dopo ogni utilizzo. Subito dopo la rimozione, utilizzare acqua calda (non superiore a 45 °C/113 °F) e sapone per rimuovere saliva e detriti residui dal dispositivo. Il produttore consiglia di non immergere il dispositivo in soluzioni che potrebbero portare alla delaminazione.

6) Conservazione

Utilizzare una custodia appositamente progettata per dispositivi dentali per proteggerli da contaminazione e danni. La custodia deve avere un buon flusso d'aria per prevenire l'accumulo di umidità.

7) Durata prevista / Servizio

Gli apparecchi per apnea notturna (apparecchi orali) durano normalmente da 2 a 5 anni, ma questa durata può variare a seconda del design e della cura. I segnali che indicano la necessità di una sostituzione includono una scarsa vestibilità, usura o una ridotta efficacia. Pertanto, controlli dentali regolari sono fondamentali per monitorare le condizioni e garantire che il dispositivo rimanga funzionale.

8) Segnalazione di incidenti / Reclami

Segnalare gli incidenti gravi sospetti associati a questo dispositivo a:

- Produttore e/o entità UE Dandy utilizzando i contatti sopra indicati e i corrispondenti requisiti locali
- L'Autorità Competente del vostro Stato Membro, conformemente al Regolamento (UE) 2017/745 (MDR).

Competent Authorities:

- France: Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
- Spain: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
- Germany : Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (BfArM)
- Italy : Ministero della Salute / Istituto Superiore di Sanità (ISS)
- Netherlands: Inspectie Gezondheidszorg en Jeugd (IGJ)
- Austria: Bundesamt für Sicherheit im Gesundheitswesen (BASG)
- Sweden: Läkemedelsverket
- Denmark: Lægemiddelstyrelsen
- Portugal: Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED)

INFORMAZIONI
Per i recapiti completi del Rappresentante Autorizzato locale, consultare la sezione: Rappresentanti Autorizzati — alla fine del documento.

9) Smaltimento

Per lo smaltimento di un apparecchio per apnea notturna, consultare principalmente il proprio dentista o utilizzare le strutture locali di smaltimento/riciclaggio di rifiuti elettronici. Non smaltirlo tra i normali rifiuti domestici a meno che non sia indicato dalle normative locali.

UNITED KINGDOM (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

United Kingdom — Custom-Made Device (CMD)

GMDN / EMDN	47526
Product Code(s)	SLEEPAPD, SLEEPAPH

Manufacturer	**Zima International, Inc. Also DBA Dandy** 1320 N. 300 W., Lehi, UT 84043 United States
UK Responsible Person (UKRP)	**Name:** DANDY LABS GB, LTD **Company No.:** Company Number: 16873608 **Address:** 5 New Street Square, London EC4A 3TW, United Kingdom

Intended User	Prescriber — Dental professional / dental practice
Device Type	Custom-made dental device (CMD)
Sterility	Not supplied sterile
Single-use / Reusable	Reusable

1) Intended Purpose (Intended Use)

A Dandy sleep apnea device is a type of dental device used to treat snoring and mild to moderate obstructive sleep apnea. It is also known as a mandibular advancement device or mandibular repositioning device.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Dandy devices are custom-made to fit your patient's mouth and are designed to be as comfortable and unobtrusive as possible.
- Material: PMMA Block or Nylon

PMMA Block

Nylon

3) Contraindications

- Sleep apnea devices may not be appropriate for individuals with severe respiratory conditions, such as severe chronic obstructive pulmonary disease (COPD), severe asthma, or other conditions that the use of positive airway pressure could exacerbate.
- Oral devices, which are used to treat sleep apnea by repositioning the jaw and tongue, may not be suitable for individuals with severe dental issues, such as untreated gum disease or extensive

tooth decay. Similarly, individuals with severe jaw problems or temporomandibular joint (TMJ) disorders may require careful evaluation to determine if an oral appliance is appropriate.

4) Warnings / Precautions / Potential Risks

⚠ WARNING

It is common for patients to experience some initial discomfort or soreness when the appliance is first placed or adjusted. This discomfort usually subsides as the patient adapts to the device.

⚠ CAUTION

na

5) Cleaning and Care

Directions for Use

To ensure proper use of the devices, follow these steps:

- Before inserting the sleep apnea device, brush and floss the teeth and rinse the mouth with water to ensure good oral hygiene and prevent any food particles from getting trapped under the device.
- The appliance is crafted to cover the upper and lower teeth and stays secure through adaptable metallic connectors. You may engage the device by means of adjustable lugs or by the Herbst® mechanism, which is a rod and tube assembly that orients the jaws in a predetermined relationship. Place the upper piece of the appliance in the patient's mouth and have the patient bite down gently to position it properly.
- The Herbst® is a one-piece construction held together by two adjustment mechanisms on the buccal or outer area of the upper and lower appliances. The adjustment mechanisms are designed for the doctor to advance the mandible to the desired position incrementally. Dorsal is a two-piece design with separate upper and lower acrylic portions that, when engaged, propel the mandible into a protrusive position via acrylic fins built in the lower acrylic portion.
- The Dorsal is an adjustable design utilizing advancement; once the upper piece is in place, insert the lower piece of the device, and then adjust the metal connectors to hold the lower jaw in a slightly advanced position. Finding the most comfortable and effective position may require some trial and error.
- The patient should breathe through their nose and ensure that the appliance is properly seated and comfortable. It may take some time to adjust to the feeling of the appliance in the mouth, but most patients find that they can sleep comfortably with it in place.
- The patient is advised to use the device according to the guidelines provided by your practice, which may encompass detailed instructions regarding the daily duration of wear and the appropriate times for removal.

Cleaning instructions

- Dandy recommends cleaning your sleep apnea device daily before and after every use. Immediately after removal, use warm water (not to exceed 45°C/113°F) and soap to remove remaining saliva and debris from the device. The manufacturer advises against immersing the device in solutions, which could lead to delamination.

6) Storage

Use a case specifically designed for dental devices to protect them from contamination and damage. The case should have good airflow to prevent moisture buildup.

7) Expected Life / Service

Sleep apnea mouth appliances (oral appliances) typically last 2 to 5 years, but this duration can vary depending on the design and care. Signs indicating the need for replacement include a poor fit, wear, or reduced effectiveness. Therefore, regular dental check-ups are crucial to monitor their condition and ensure they remain functional.

8) Incident / Complaint Reporting

Report suspected serious incidents associated with this device to:

- The Manufacturer and/or UK Responsible Person (UKRP) using the contacts above, and
- The UK Medicines and Healthcare products Regulatory Agency (MHRA) — www.gov.uk/mhra

In accordance with The Medical Devices Regulations 2002 (as amended).

> **INFO**
> For full contact details of the local Authorized Representative, refer to: Authorized Representatives — end of this document.

9) Disposal

To dispose of a sleep apnea oral appliance, you should primarily consult with your dental specialist or use local e-waste/recycling facilities. Do not dispose of it with regular household trash unless directed by local regulations.

AUTHORIZED REPRESENTATIVES / REPRÉSENTANTS AUTORISÉS / BEVOLLMÄCHTIGTE VERTRETER / RAPPRESENTANTI AUTORIZZATI / REPRESENTANTES AUTORIZADOS

The table below lists the local Authorized Representative or Sponsor for each country / jurisdiction where this device is marketed. For incident reporting, contact the representative for your country.

La tabla siguiente enumera el Representante Autorizado o Patrocinador local para cada país. | Le tableau ci-dessous liste le Représentant Autorisé local pour chaque pays. | Die folgende Tabelle enthält die bevollmächtigten Vertreter je Land.

Jurisdiction	Authorised Rep / Sponsor	Registered Address / Contact Email	Reg. Number	Regulatory Body
Australia (AUS)	DANDY Labs AUS Pty Ltd	Tower One, Level 46, 100 Barangaroo Ave, Sydney NSW 2000 Compliance@meetdandy.com	ABN: 33693955761	TGA (Therapeutic Goods Administration)
EU — English	Dandy Labs Europe	3, boulevard de Sebastopol, 75001 Paris, France Compliance@meetdandy.com	Reg: 989857065	Competent Authority / EUDAMED
EU — España	Dandy Labs Europa	3, boulevard de Sebastopol, 75001 París, Francia Compliance@meetdandy.com	Reg: 989857065	AEMPS / Autoridad Competente
EU — France	Dandy Labs Europe	3, boulevard de Sebastopol, 75001 Paris, France Compliance@meetdandy.com	Reg: 989857065	ANSM / Autorité Compétente
EU — Deutschland	Dandy Labs Europe	3, boulevard de Sebastopol, 75001 Paris, Frankreich Compliance@meetdandy.com	Reg: 989857065	BfArM / Zuständige Behörde
EU — Italia	Dandy Labs Europe	3, boulevard de Sebastopol, 75001 Parigi, Francia Compliance@meetdandy.com	Reg: 989857065	Min. della Salute / ISS
United Kingdom (UK)	DANDY LABS GB, LTD	5 New Street Square, London EC4A 3TW Compliance@meetdandy.com	Co. No.: 16873608	MHRA

NOTE

Contact details are subject to change. Always verify current information on the official product labelling or the manufacturer's website before reporting an incident. / Les coordonnées sont susceptibles de changer. / Angaben können sich ändern. / I recapiti sono soggetti a modifiche.

Manufacturer / Hersteller / Fabbricante / Fabricant / Fabricante	**Zima International, Inc. Also DBA Dandy** 1320 N. 300 W., Lehi, UT 84043, United States compliance@meetdandy.com

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Approve	Kasha Lim	Supplier Quality Engineer	18-Jun-2026 06:41

* Datetime fields are displayed according to the system time zone: (GMT-04:00) Eastern Daylight Time (America/New_York)