



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	MouthGuard
GMDN / EMDN Code	38620
Product Code(s)	NIGHTGRDS, THERMONGH, THERMONGS, THERMONGHS, THERMONGA, THERMONGNTI, THERMOSG, THERMOHFA, THERMOHOS, THERMONGS, THERMOHSOS, THERMOHSFA, THERMONGA, THERMONGNTI, THERMOSFA
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	38620
Product Code(s)	NIGHTGRDS, THERMONGH, THERMONGS, THERMONGHS, THERMONGA, THERMONGNTI, THERMOSG, THERMOHFA, THERMOHOS, THERMONGS, THERMOHSOS, THERMOHSFA, THERMONGA, THERMONGNTI, THERMOSFA
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)

The device is made of biocompatible materials and is custom-made for each patient. The nightguard fits comfortably over the upper or lower teeth and provides protection against damage caused by bruxism.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Hard, Soft, and Dual-Laminated Night Guards (Thermoformed) are dental devices that protect teeth from nighttime grinding and clenching.
- Material: Hard, Soft, Hard/Soft, Astron, and 3D Printed

[Erkoflex Thermoforming Discs - Soft](#)

[Erkoflex Thermoforming Discs - Hard](#)

[Erkoflex Thermoforming Discs - Hard/Soft](#)

[Clearsplint - Powder](#)

[Clearsplint - Liquid](#)

[Keysplint](#)

3) Contraindications

Patients with loose or damaged teeth or those with temporomandibular joint disorder (TMD) should not use the device without first consulting a dental professional.

4) Warnings / Precautions / Potential Risks

⚠ WARNING

The potential risks include mouth or tooth soreness, which should resolve after a few days of use.

⚠ CAUTION

NA

5) Cleaning and Care

Directions for Use

- Wash your hands before handling the nightguard.
- Place the nightguard over the upper or lower teeth as the dentist instructs.
- Bite down gently to ensure a comfortable fit.
- Remove the nightguard in the morning and rinse with warm water.

Cleaning instructions

- Dandy recommends cleaning your device daily before and after every use. Immediately after removal,
- Use warm water (not to exceed 45°C/113°F) and dishwashing soap to remove remaining saliva and debris from the device.

Only use soft, antibacterial dish soap (liquid)

- Do not use flavored or scented soaps
- Do not use soaps with heavy dyes and colors
- Rinse the device thoroughly with cool water.
- Do not use hot water, as it can warp the device.
- Do not use mouthwash, as it can discolor the device.

Clean the device daily.

USING CLEANING AGENTS

- For periodic debris removal and maintenance, use a soft bristle brush to clean the inside of your appliance for debris removal.
- The product should be cleaned with antibacterial cleaning solutions like Polident and Efferdent.
- These cleaners are designed for use in brief sessions of 10–15 minutes.
- Always make sure to follow the manufacturer's instructions for proper use.

Do not use:

- Avoid immersing the product in, or cleaning it with, any of the following substances: sodium hypochlorite (chlorine bleach), hydrogen peroxide, mouthwash, or alcohol products. Using these can lead to discoloration and damage to the material.

6) Storage

The device should be stored in a dry, clean container when not in use.

7) Expected Life / Service

.A mouthguard's life expectancy varies by type: 1-5 years for durable custom-fit guards, depending heavily on usage, material, and care, with heavy grinding or poor cleaning shortening their lifespan significantly and making them less protective. Regular checks for cracks, fit, odor, or damage are key indicators for replacement, ensuring consistent protection against sports impacts or teeth grinding (bruxism).

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

Specialized services handle biohazardous waste, but for home users, standard household disposal is key. This involves keeping it out of landfills whenever possible, and definitely out of sewers and recycling facilities.

EUROPEAN UNION (ENGLISH)**INSTRUCTIONS FOR USE (IFU)**

European Union — Custom-Made Device (CMD)

GMDN / EMDN	Q0199 - ODONTOLOGY DEVICES - OTHER
Product Code(s)	NIGHTGRDS, THERMONGH, THERMONGS, THERMONGHS, THERMONGA, THERMONGNTI, THERMOSG, THERMOHFA, THERMOHOS, THERMONGS, THERMOHSOS, THERMOHSFA, THERMONGA, THERMONGNTI, THERMOSFA
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)

The device is made of biocompatible materials and is custom-made for each patient. The nightguard fits comfortably over the upper or lower teeth and provides protection against damage caused by bruxism.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Hard, Soft, and Dual-Laminated Night Guards (Thermoformed) are dental devices that protect teeth from nighttime grinding and clenching.
- Material: Hard, Soft, Hard/Soft, Astron, and 3D Printed

[Erkoflex Thermoforming Discs - Soft](#)

[Erkoflex Thermoforming Discs - Hard](#)

[Erkoflex Thermoforming Discs - Hard/Soft](#)

[Clearsplint - Powder](#)

[Clearsplint - Liquid](#)

[Keysplint](#)

3) Contraindications

Patients with loose or damaged teeth or those with temporomandibular joint disorder (TMD) should not use the device without first consulting a dental professional.

4) Warnings / Precautions / Potential Risks

⚠ WARNING

The potential risks include mouth or tooth soreness, which should resolve after a few days of use.

⚠ CAUTION

[Insert precaution text]

5) Cleaning and Care

Directions for Use

- Wash your hands before handling the nightguard.
- Place the nightguard over the upper or lower teeth as the dentist instructs.
- Bite down gently to ensure a comfortable fit.
- Remove the nightguard in the morning and rinse with warm water.

Cleaning instructions

- Dandy recommends cleaning your device daily before and after every use. Immediately after removal,
- Use warm water (not to exceed 45°C/113°F) and dishwashing soap to remove remaining saliva and debris from the device.

Only use soft, antibacterial dish soap (liquid)

- Do not use flavored or scented soaps
- Do not use soaps with heavy dyes and colors
- Rinse the device thoroughly with cool water.
- Do not use hot water, as it can warp the device.
- Do not use mouthwash, as it can discolor the device.

Clean the device daily.

USING CLEANING AGENTS

- For periodic debris removal and maintenance, use a soft bristle brush to clean the inside of your appliance for debris removal.
- The product should be cleaned with antibacterial cleaning solutions like Polident and Efferdent.
- These cleaners are designed for use in brief sessions of 10–15 minutes.
- Always make sure to follow the manufacturer's instructions for proper use.

Do not use:

- Avoid immersing the product in, or cleaning it with, any of the following substances: sodium hypochlorite (chlorine bleach), hydrogen peroxide, mouthwash, or alcohol products. Using these can lead to discoloration and damage to the material.

6) Storage

The device should be stored in a dry, clean container when not in use.

7) Expected Life / Service

A mouthguard's life expectancy varies by type: 1-5 years for durable custom-fit guards, depending heavily on usage, material, and care, with heavy grinding or poor cleaning shortening their lifespan significantly and making them less protective. Regular checks for cracks, fit, odor, or damage are key

indicators for replacement, ensuring consistent protection against sports impacts or teeth grinding (bruxism).

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)
- Spain : Spanish Agency for Medicines and Health Products (AEMPS)
- 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) for Spain
- 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

Specialized services handle biohazardous waste, but for home users, standard household disposal is key. This involves keeping it out of landfills whenever possible, and definitely out of sewers and recycling facilities.

UNIÓN EUROPEA (ESPAÑOL)**INSTRUCCIONES DE USO (IFU)**

Unión Europea — Producto Sanitario a Medida (CMD)

GMDN / EMDN	Q0199 - DISPOSITIVOS DE ODONTOLOGÍA - OTROS
Código(s) del producto	NIGHTGRDS, THERMONGH, THERMONGS, THERMONGHS, THERMONGA, THERMONGNTI, THERMOSG, THERMOHFA, THERMOHOS, THERMONGS, THERMOHSOS, THERMOHSFA, THERMONGA, THERMONGNTI, THERMOSFA
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 Nº 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)

El dispositivo está fabricado con materiales biocompatibles y se realiza a medida para cada paciente. El protector nocturno se adapta cómodamente a los dientes superiores o inferiores y proporciona protección frente a los daños causados por el bruxismo.

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 protectores nocturnos duros, blandos y de doble laminado (termoformados) son dispositivos dentales que protegen los dientes frente al rechinar y el apretamiento nocturnos.
- Material: Duro, blando, duro/blando, Astron e impreso en 3D

[Discos de termoformado Erkoflex - blando](#)[Discos de termoformado Erkoflex - duro](#)[Discos de termoformado Erkoflex - duro/blando](#)[Clearsplint - Pol vo](#)[Clearsplint - Líquido](#)[Keysplint](#)

3) Contraindicaciones

Los riesgos potenciales incluyen molestias bucales o dentarias, que deberían resolverse tras unos días de uso.

4) Advertencias / Precauciones / Riesgos potenciales

⚠ ADVERTENCIAS

Los riesgos potenciales incluyen dolor bucal o dental, que debe resolverse después de unos días de uso.

⚠ PRECAUCIONES

NA

5) Limpieza y cuidado

Instrucciones de uso

- Lávese las manos antes de manipular el protector nocturno.
- Coloque el protector nocturno sobre los dientes superiores o inferiores como le indique el dentista.
- Muerda suavemente para asegurar un ajuste cómodo.
- Retire el protector nocturno por la mañana y enjuague con agua tibia.

Instrucciones de limpieza

- Dandy recomienda limpiar el dispositivo diariamente antes y después de cada uso. Inmediatamente después de retirarlo,
- Utilice agua tibia (sin superar los 45 °C/113 °F) y jabón lavavajillas para eliminar los restos de saliva y residuos del dispositivo.

Utilice únicamente jabón lavavajillas líquido suave y antibacteriano.

- No utilice jabones aromatizados o perfumados.
- No utilice jabones con colorantes intensos.
- Enjuague bien el dispositivo con agua fría.
- No utilice agua caliente, ya que puede deformar el dispositivo.
- No utilice enjuague bucal, ya que puede decolorar el dispositivo.

Limpie el dispositivo a diario.

USO DE AGENTES DE LIMPIEZA

- Para la eliminación periódica de residuos y el mantenimiento, utilice un cepillo de cerdas suaves para limpiar la parte interna del aparato.
- El producto debe limpiarse con soluciones limpiadoras antibacterianas como Polident y Efferdent.
- Estos limpiadores están diseñados para utilizarse en sesiones breves de 10 a 15 minutos.
- Asegúrese siempre de seguir las instrucciones del fabricante para un uso adecuado.

No utilice:

- Evite sumergir el producto o limpiarlo con cualquiera de las siguientes sustancias: hipoclorito de sodio (lejía con cloro), peróxido de hidrógeno, enjuague bucal o productos con alcohol. Su uso puede provocar decoloración y dañar el material.

6) Almacenamiento

El producto debe limpiarse con soluciones limpiadoras antibacterianas como Polident y Efferdent.

7) Vida esperada / Servicio

La vida útil de un protector bucal varía según el tipo: entre 1 y 5 años en el caso de protectores a medida duraderos, dependiendo en gran medida del uso, el material y los cuidados; el bruxismo intenso o una limpieza deficiente pueden acortar significativamente su vida útil y reducir su capacidad de protección. Las revisiones periódicas para detectar grietas, comprobar el ajuste y observar olores o daños son indicadores clave para su sustitución y garantizan una protección constante frente a impactos deportivos o al rechinar dental (bruxismo).

8) Notificación de incidentes / Reclamaciones

Comuniqué 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)
- Spain : Spanish Agency for Medicines and Health Products (AEMPS)
- 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) for Spain
- 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

Los residuos biopeligrosos deben ser gestionados por servicios especializados, pero para los usuarios domésticos la clave es una eliminación correcta en el hogar. Esto implica evitar, siempre que sea posible, su eliminación en vertederos y, en cualquier caso, no desecharlos por el desagüe ni en instalaciones de reciclaje.

UNION EUROPÉENNE (FRANÇAIS)**INSTRUCTIONS D'UTILISATION (IFU)**

Union Européenne — Dispositif sur Mesure (CMD)

GMDN / EMDN	Q0199 - DISPOSITIFS ODONTOLOGIQUES - AUTRES
Code(s) produit	NIGHTGRDS, THERMONGH, THERMONGS, THERMONGHS, THERMONGA, THERMONGNTI, THERMOSG, THERMOHFA, THERMOHOS, THERMONGS, THERMOHSOS, THERMOHSFA, THERMONGA, THERMONGNTI, THERMOSFA
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)

Le dispositif est fabriqué à partir de matériaux biocompatibles et est fabriqué sur mesure pour chaque patient. La gouttière nocturne s'adapte confortablement sur les dents du haut ou du bas et protège contre les dommages causés par le bruxisme.

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 gouttières de nuit rigides, souples et à double stratification (thermoformées) sont des dispositifs dentaires qui protègent les dents contre le grincement et le serrement nocturnes.
- Matériel : Rigide, souple, rigide/souple, Astron et imprimé en 3D

[Disques de thermoformage Erkoflex - Souple](#)

[Disques de thermoformage Erkoflex - Rigide](#)

[Disques de thermoformage Erkoflex - Rigide/souple](#)

[Clearsplint - Poudre](#)

[Clearsplint - Liquide](#)

[Keysplint](#)

3) Contre-indications

Les patients présentant des dents amovibles ou abîmées, ou ceux souffrant d'un trouble de l'articulation temporo-mandibulaire (ATM), ne doivent pas utiliser cet appareil sans avoir préalablement consulté un professionnel dentaire.

4) Avertissements / Précautions / Risques potentiels

⚠ Avertissements

Les risques potentiels comprennent des douleurs buccodentaires, qui devraient disparaître après quelques jours d'utilisation.

⚠ Précautions

NA

5) Nettoyage et entretien

Mode d'emploi

- Se laver les mains avant de manipuler la gouttière nocturne.
- Placer la gouttière nocturne sur les dents du haut ou du bas, selon les instructions du dentiste.
- Mordre doucement pour vérifier que l'ajustement est confortable.
- Retirer la gouttière la matin et la rincer à l'eau tiède.

Instructions de nettoyage

- Dandy recommande de nettoyer votre appareil 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 liquide vaisselle pour éliminer les résidus de salive et les impuretés présents sur l'appareil.

Utiliser uniquement du liquide vaisselle doux et antibactérien (liquide)

- Ne pas utiliser de savons parfumés ou parfumés.
- Ne pas utiliser de savons contenant des colorants ou des pigments trop concentrés.
- Rincer soigneusement le dispositif à l'eau froide.
- Ne pas utiliser d'eau chaude, car elle peut déformer l'appareil.
- Ne pas utiliser de bain de bouche, car il peut décolorer l'appareil.

Nettoyer le dispositif quotidiennement.

UTILISATION D'AGENTS NETTOYANTS

- Pour l'entretien régulier et l'élimination des résidus, utiliser une brosse à poils souples pour nettoyer l'intérieur de votre appareil et éliminer les résidus.
- Le produit doit être nettoyé avec des solutions de nettoyage antibactériennes telles que Polident et Efferdent.
- Ces nettoyants sont conçus pour être utilisés pendant de brèves séances de 10 à 15 minutes.
- Veiller à toujours suivre les instructions du fabricant pour une utilisation correcte.

Ne pas utiliser :

- Éviter d'immerger le produit ou de le nettoyer avec l'une des substances suivantes : hypochlorite de sodium (eau de Javel chlorée), peroxyde d'hydrogène, bain de bouche ou produits alcoolisés. Leur utilisation peut entraîner une décoloration et des dommages au matériau.

6) Stockage

L'appareil doit être stocké dans un récipient sec et propre lorsqu'il n'est pas utilisé.

7) Durée de vie / Service attendu

La durée de vie d'un protège-dents varie selon le type : 1 à 5 ans pour les protège-dents sur mesure résistants, en fonction principalement de l'utilisation, du matériau et de l'entretien ; un frottement intense ou un mauvais nettoyage réduisent considérablement leur durée de vie et diminuent leur efficacité protectrice. Des contrôles réguliers visant à détecter d'éventuelles fissures, à vérifier l'ajustement, à détecter des odeurs ou des dommages constituent des indicateurs clés justifiant un remplacement, garantissant ainsi une protection constante contre les chocs liés à la pratique sportive ou le grincement des dents (bruxisme).

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 applicables
- 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)
- Spain : Spanish Agency for Medicines and Health Products (AEMPS)
- 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) for Spain
- 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

Des services spécialisés se chargent des déchets biologiques dangereux, mais pour les particuliers, il est essentiel de les éliminer via les filières de collecte ménagères habituelles. Il s'agit donc de les éviter autant que possible dans les décharges, et surtout de ne pas les jeter dans les égouts ni dans les centres de recyclage.

EUROPÄISCHE UNION (DEUTSCH)**GEBRAUCHSANWEISUNG (IFU)**

EU-SONDERANFERTIGUNG (CMD – Sonderanfertigung)

GMDN / EMDN	Q0199 – ZAHNÄRZTLICHE MEDIZINPRODUKTE – SONSTIGE
Produktcode(s)	NIGHTGRDS, THERMONGH, THERMONGS, THERMONGHS, THERMONGA, THERMONGNTI, THERMOSG, THERMOHFA, THERMOHOS, THERMONGS, THERMOHSOS, THERMOHSFA, THERMONGA, THERMONGNTI, THERMOSFA
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)

Die Apparatur besteht aus biokompatiblen Materialien und ist für jeden Patienten maßgefertigt / eine Sonderanfertigung. Die Aufbissschiene passt bequem über die Ober- oder Unterkieferzähne und bietet Schutz vor Schäden, die durch Bruxismus verursacht werden.

2) Produktbeschreibung / Hauptspezifikationen

- Maßgefertigte, patientenspezifische Sonderanfertigung, hergestellt nach zahnärztlicher Verordnung und digitalen Eingabedaten.
- Konfiguration: Harte, weiche und dual-laminierte Aufbissschienen (tiefgezogen) sind zahnmedizinische Produkte, die die Zähne vor nächtlichem Knirschen und Aufeinanderpressen schützen.
- Material: Hart, Weich, Hart/weich, Astron und 3D-gedruckt

[Erkoflex Tiefziehfolien – weich](#)[Erkoflex Tiefziehfolien – hart](#)[Erkoflex Tiefziehfolien – hart/weich](#)[CLEARsplint – Pulver](#)[CLEARsplint – Flüssigkeit](#)[KeySplint](#)

3) Kontraindikationen

Patienten mit lockeren oder beschädigten Zähnen oder Personen mit einer Erkrankung des Kiefergelenks (CMD) sollten das Produkt nicht ohne vorherige Konsultation eines Zahnarztes anwenden.

4) Warnhinweise / Vorsichtsmaßnahmen / Potenzielle Risiken

WARNHINWEISE

Zu den möglichen Risiken gehören Schmerzen im Mund bzw. Zahnschmerzen, die nach einigen Tagen der Anwendung abklingen sollten.

VORSICHTSMASSNAHMEN

NA

5) Reinigung und Pflege

Gebrauchsanleitung

- Waschen Sie sich vor der Handhabung der Aufbissschiene die Hände.
- Setzen Sie die Aufbissschiene entsprechend der Anweisung des Zahnarztes auf die Ober- oder Unterkieferzähne.
- Beißen Sie leicht zu, um einen bequemen Sitz zu überprüfen.
- Nehmen Sie die Aufbissschiene am Morgen heraus und spülen Sie sie mit warmem Wasser ab.

Reinigungsanleitung

- Dandy empfiehlt, Ihre Apparatur täglich sowie vor und nach jedem Gebrauch zu reinigen. Direkt nach dem Herausnehmen: Verwenden Sie warmes Wasser (nicht über 45 °C / 113 °F) und Spülmittel, um verbleibenden Speichel und Rückstände vom Produkt zu entfernen.

Verwenden Sie ausschließlich ein mildes, antibakterielles Mittel (Flüssigspülseife).

- Keine parfümierten oder mit Aromen versetzten Seifen verwenden
- Keine Seifen mit starken Farbstoffen und Farben verwenden
- Spülen Sie die Apparatur gründlich mit kaltem Wasser ab.
- Verwenden Sie kein heißes Wasser, da sich die Apparatur dadurch verziehen kann.
- Verwenden Sie kein Mundwasser, da dies zu Verfärbungen des Produkts führen kann.

Reinigen Sie die Apparatur täglich.

VERWENDUNG VON REINIGUNGSMITTELN

- Verwenden Sie zur regelmäßigen Entfernung von Ablagerungen und zur Pflege eine Bürste mit weichen Borsten, um die Innenseite Ihres Hilfsmittels von Verunreinigungen zu befreien.
- Das Produkt sollte mit antibakteriellen Reinigungslösungen wie Polident und Efferdent gereinigt werden.
- Diese Reiniger sind für eine kurze Anwendung von 10–15 Minuten konzipiert.
- Achten Sie immer darauf, die Anweisungen des Herstellers für eine ordnungsgemäße Verwendung zu befolgen.

Nicht verwenden:

- Das Produkt nicht in folgende Substanzen eintauchen oder es damit reinigen: Natriumhypochlorit (Chlorbleiche), Wasserstoffperoxid, Mundspülung oder alkoholhaltige Produkte. Die Verwendung dieser Mittel kann zu Verfärbungen und Schäden am Material führen.

6) Lagerung

Das Gerät sollte in einem trockenen, sauberen Behälter aufbewahrt werden, wenn es nicht verwendet wird.

7) Erwartete Lebensdauer / Nutzungsdauer

Die Lebenserwartung eines Mundschutzes variiert je nach Typ: 1 bis 5 Jahre bei langlebigen, individuell angepassten Schienen – stark abhängig von Nutzung, Material und Pflege, wobei starkes Zähneknirschen oder mangelhafte Reinigung ihre Lebensdauer erheblich verkürzen und ihre Schutzwirkung verringern. Regelmäßige Kontrollen auf Risse, Passform, Geruch oder Beschädigungen sind wichtige Indikatoren für einen Austausch, um einen gleichbleibenden Schutz vor Sportverletzungen oder Zähneknirschen (Bruxismus) 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)
- Spain : Spanish Agency for Medicines and Health Products (AEMPS)
- 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) for Spain
- 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

Spezialisierte Dienstleister übernehmen die Entsorgung von biologischem Abfall, während für Heimanwender die Entsorgung über den normalen Hausmüll maßgeblich ist. Dazu gehört, dafür zu sorgen, dass das Produkt nach Möglichkeit nicht auf Deponien und in jedem Fall nicht in die Kanalisation sowie Recyclinganlagen gelangt.

UNIONE EUROPEA (ITALIANO)

ISTRUZIONI PER L'USO (IFU)

DISPOSITIVO PERSONALIZZATO UE (CMD = Dispositivo personalizzato)

GMDN / EMDN	Q0199 – DISPOSITIVI PER ODONTOIATRIA – ALTRO
Codice(i) prodotto	NIGHTGRDS, THERMONGH, THERMONGS, THERMONGHS, THERMONGA, THERMONGNTI, THERMOSG, THERMOHFA, THERMOHOS, THERMONGS, THERMOHSOS, THERMOHSFA, THERMONGA, THERMONGNTI, THERMOSFA
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)

Il dispositivo è realizzato con materiali biocompatibili ed è fatto su misura per ogni paziente. La night guard si adatta comodamente ai denti superiori o inferiori e offre protezione contro i danni causati dal bruxismo.

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: Le night guard dure, morbide e bilaminare (termoformate) sono dispositivi dentali che proteggono i denti dal digrignamento e dalle tensioni notturne.
- Materiale: duro, morbido, duro/morbido, Astron e stampato 3D.

[Dischi termoformanti Erkoflex – Morbidi](#)

[Dischi termoformanti Erkoflex – Duri](#)

[Dischi termoformanti Erkoflex – Duri/Morbidi](#)

[Clearsplint – Polvere](#)

[Clearsplint – Liquido](#)

[Keysplint](#)

3) Controindicazioni

Pazienti con denti allentati o danneggiati o quelli con disturbo dell'articolazione temporo-mandibolare (TMD) non devono utilizzare il dispositivo senza aver prima consultato un odontoiatra.

4) Avvertenze / Precauzioni / Rischi potenziali

⚠ AVVERTENZE

I rischi potenziali includono dolore alla bocca o ai denti, che dovrebbe risolversi dopo alcuni giorni di utilizzo.

⚠ PRECAUZIONI

NA

5) Pulizia e cura

Istruzioni per l'uso

- Lavarsi le mani prima di maneggiare il night guard.
- Posizionare il night guard sui denti superiori o inferiori come indicato dal dentista.
- Mordere delicatamente per garantire una vestibilità confortevole.
- Rimuovere il night guard al mattino e sciacquare con acqua calda.

Istruzioni per la pulizia

- Dandy consiglia di pulire il dispositivo ogni giorno prima e dopo ogni utilizzo. Subito dopo la rimozione, utilizzare acqua calda (non superiore a 45 °C/113 °F) e detersivo per i piatti per rimuovere saliva e detriti residui dal dispositivo.

Usare solo detersivo per piatti antibatterico e delicato (liquido).

- Non utilizzare detersivi aromatizzati o profumati.
- Non utilizzare detersivi con coloranti e colori intensi.
- Sciacquare accuratamente il dispositivo con acqua fredda.
- Non utilizzare acqua bollente, in quanto è in grado di deformare il dispositivo.
- Non utilizzare collutorio, poiché può scolorire il dispositivo.

Pulire il dispositivo ogni giorno.

USO DI DETERGENTI

- Per la rimozione e la manutenzione periodiche dei detriti, usare uno spazzolino a setole morbide per pulire l'interno dell'apparecchio per la rimozione dei detriti.
- Il prodotto deve essere pulito con soluzioni detergenti antibatteriche come Polident ed Efferdent.
- Questi detergenti sono progettati per l'uso per brevi sessioni di 10-15 minuti.
- Accertarsi sempre di seguire le istruzioni del produttore per un uso corretto.

Non utilizzare:

- Evitare di immergere il prodotto o di pulirlo con una delle seguenti sostanze: ipoclorito di sodio (candeggina), perossido di idrogeno, collutorio o prodotti a base alcolica. L'uso di queste sostanze può causare scolorimento e danni al materiale.

6) Conservazione

Il dispositivo deve essere conservato in un contenitore asciutto e pulito quando non utilizzato

7) Durata prevista / Servizio

La durata prevista di un paradenti varia in base al tipo: 1-5 anni per protezioni personalizzate resistenti, a seconda dell'uso, del materiale e della cura, con digrignamento intenso o pulizia inadeguata che accorciano significativamente la durata e le rendono meno protettive. I controlli regolari di eventuali incrinature, vestibilità, odore o danni sono indicatori chiave per la sostituzione, garantendo una protezione coerente contro gli impatti sportivi o il digrignamento dei denti (bruxismo).

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 : Spanish Agency for Medicines and Health Products (AEMPS)
- 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) for Spain
- 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

I servizi specializzati gestiscono i rifiuti a rischio biologico, ma per gli utenti domestici, lo smaltimento domestico standard è fondamentale. Ciò significa non portare il dispositivo in discarica quando possibile, e sicuramente non metterlo nelle fogne e negli impianti di riciclaggio.

UNITED KINGDOM (ENGLISH)**INSTRUCTIONS FOR USE (IFU)**

United Kingdom — Custom-Made Device (CMD)

GMDN / EMDN	38620
Product Code(s)	NIGHTGRDS, THERMONGH, THERMONGS, THERMONGHS, THERMONGA, THERMONGNTI, THERMOSG, THERMOHFA, THERMOHOS, THERMONGS, THERMOHSOS, THERMOHSFA, THERMONGA, THERMONGNTI, THERMOSFA
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)

The device is made of biocompatible materials and is custom-made for each patient. The nightguard fits comfortably over the upper or lower teeth and provides protection against damage caused by bruxism.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Hard, Soft, and Dual-Laminated Night Guards (Thermoformed) are dental devices that protect teeth from nighttime grinding and clenching.
- Material: Hard, Soft, Hard/Soft, Astron, and 3D Printed

[Erkoflex Thermoforming Discs - Soft](#)

[Erkoflex Thermoforming Discs - Hard](#)

[Erkoflex Thermoforming Discs - Hard/Soft](#)

[Clearsplint - Powder](#)

[Clearsplint - Liquid](#)

[Keysplint](#)

3) Contraindications

Patients with loose or damaged teeth or those with temporomandibular joint disorder (TMD) should not use the device without first consulting a dental professional.

4) Warnings / Precautions / Potential Risks

WARNING

The potential risks include mouth or tooth soreness, which should resolve after a few days of use.

CAUTION

NA

5) Cleaning and Care

Directions for Use

- Wash your hands before handling the nightguard.
- Place the nightguard over the upper or lower teeth as the dentist instructs.
- Bite down gently to ensure a comfortable fit.
- Remove the nightguard in the morning and rinse with warm water.

Cleaning instructions

- Dandy recommends cleaning your device daily before and after every use. Immediately after removal,
- Use warm water (not to exceed 45°C/113°F) and dishwashing soap to remove remaining saliva and debris from the device.

Only use soft, antibacterial dish soap (liquid)

- Do not use flavored or scented soaps
- Do not use soaps with heavy dyes and colors
- Rinse the device thoroughly with cool water.
- Do not use hot water, as it can warp the device.
- Do not use mouthwash, as it can discolor the device.

Clean the device daily.

USING CLEANING AGENTS

- For periodic debris removal and maintenance, use a soft bristle brush to clean the inside of your appliance for debris removal.
- The product should be cleaned with antibacterial cleaning solutions like Polident and Efferdent.
- These cleaners are designed for use in brief sessions of 10–15 minutes.
- Always make sure to follow the manufacturer's instructions for proper use.

Do not use:

- Avoid immersing the product in, or cleaning it with, any of the following substances: sodium hypochlorite (chlorine bleach), hydrogen peroxide, mouthwash, or alcohol products. Using these can lead to discoloration and damage to the material.

6) Storage

The device should be stored in a dry, clean container when not in use.

7) Expected Life / Service

A mouthguard's life expectancy varies by type: 1-5 years for durable custom-fit guards, depending heavily on usage, material, and care, with heavy grinding or poor cleaning shortening their lifespan significantly and making them less protective. Regular checks for cracks, fit, odor, or damage are key indicators for replacement, ensuring consistent protection against sports impacts or teeth grinding (bruxism).

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

Specialized services handle biohazardous waste, but for home users, standard household disposal is key. This involves keeping it out of landfills whenever possible, and definitely out of sewers and recycling facilities.

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 /
Fabbicante / 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	12-Jun-2026 01:55

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