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	Denture Reliner - Hard
GMDN / EMDN Code	17609
Product Code(s)	ACRFDENTRLN, DENTFLRLN, MILLDENTRLN
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	17609
Product Code(s)	ACRFDENTRLN, DENTFLRLN, MILLDENTRLN

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)

This custom-made denture reliner is intended to improve denture fit/retention when a denture no longer fits as intended and requires relining, as prescribed by a licensed dental professional.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Hard denture reline (full arch) (as applicable)
- Material: Sofreliner (Silicone Dioxide)

Liner Material Safety Data Sheets (Paste)
Liner Material Safety Data Sheets (Primer)

3) Contraindications

Do not use in patients with:

- Known hypersensitivity to the device material
- Untreated oral lesions

4) Warnings / Precautions / Potential Risks

⚠ WARNING

Potential risks associated with denture lining materials may include:

- Gingival irritation, mucosal soreness, ulceration
- Poor adaptation may cause instability or trauma
- Allergic response
- Separation of material

If the patient experiences pain, irritation, or other adverse effects, discontinue use and contact the treating dental professional.

⚠ CAUTION

NA

5) Cleaning and Care

Daily cleaning:

- Brush gently using a soft-bristled denture brush or soft toothbrush.
- Avoid abrasive products (e.g., toothpaste, abrasive cleaners, strong soaps).
- Use mild, non-abrasive liquid dish soap as directed by the dental professional.
- Rinse thoroughly under cool or lukewarm running water.
- Avoid high heat; do not use hot or boiling water.

Soaking:

- Store/soak as directed by the dental professional to prevent drying.
- Avoid prolonged soaking in effervescent cleaners if this may damage the material.

Do not use:

- Avoid cleaning/immersing the device in sodium hypochlorite (chlorine bleach), hydrogen peroxide, mouthwash, or alcohol products, as these may damage or discolour the material.

6) Storage

When not in use, store the device as directed by the dental professional. Avoid excessive heat, pressure, or conditions that may deform or damage the device.

7) Expected Life / Service

With appropriate care and maintenance, the device is intended for ongoing use as directed by the dental professional. If the device becomes damaged or fit is no longer acceptable, the patient should contact their treating dental professional for evaluation.

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

Dispose of the device in accordance with local regulations and the dental practice's procedures. If the device is contaminated with bodily fluids, treat it as clinical/infectious waste per local requirements.

EUROPEAN UNION (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

European Union — Custom-Made Device (CMD)

GMDN / EMDN	Q01020601: Mobile Dental Prostheses
Product Code(s)	ACRFDENTRLN, DENTFLRLN, MILLDENTRLN

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)

This custom-made denture reliner is intended to improve denture fit/retention when a denture no longer fits as intended and requires relining, as prescribed by a licensed dental professional.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Hard denture reline (full arch) (as applicable)
- Material: Sofreliner (Silicone Dioxide)

Liner Material Safety Data Sheets (Paste)
Liner Material Safety Data Sheets (Primer)

3) Contraindications

Do not use in patients with:

- Known hypersensitivity to the device material
- Untreated oral lesions

4) Warnings / Precautions / Potential Risks

⚠ WARNING

Potential risks associated with denture lining materials may include:

- Gingival irritation, mucosal soreness, ulceration
- Poor adaptation may cause instability or trauma
- Allergic response
- Separation of material

If the patient experiences pain, irritation, or other adverse effects, discontinue use and contact the treating dental professional.

⚠ CAUTION

NA

5) Cleaning and Care

Daily cleaning:

- Brush gently using a soft-bristled denture brush or soft toothbrush.
- Avoid abrasive products (e.g., toothpaste, abrasive cleaners, strong soaps).
- Use mild, non-abrasive liquid dish soap as directed by the dental professional.
- Rinse thoroughly under cool or lukewarm running water.
- Avoid high heat; do not use hot or boiling water.

Soaking:

- Store/soak as directed by the dental professional to prevent drying.
- Avoid prolonged soaking in effervescent cleaners if this may damage the material.

Do not use:

- Avoid cleaning/immersing the device in sodium hypochlorite (chlorine bleach), hydrogen peroxide, mouthwash, or alcohol products, as these may damage or discolour the material.

6) Storage

When not in use, store the device as directed by the dental professional. Avoid excessive heat, pressure, or conditions that may deform or damage the device.

7) Expected Life / Service

With appropriate care and maintenance, the device is intended for ongoing use as directed by the dental professional. If the device becomes damaged or fit is no longer acceptable, the patient should contact their treating dental professional for evaluation.

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 the full contact information of the local Authorized Representative, see: Authorized Representatives — at the end of the document.

9) Disposal

Dispose of the device in accordance with local regulations and the dental practice’s procedures. If the device is contaminated with bodily fluids, treat it as clinical/infectious waste per local requirements.

UNIÓN EUROPEA (ESPAÑOL)

INSTRUCCIONES DE USO (IFU)

Unión Europea — Producto Sanitario a Medida (CMD)

GMDN / EMDN	Q01020601: Prótesis dentales móviles
Código(s) del producto	ACRFDENTRLN, DENTFLRLN, MILLDENTRLN

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)

Este rebase de prótesis a medida está diseñado para mejorar el ajuste y la retención de la prótesis cuando ésta deja de ajustarse correctamente y requiere un rebase, según prescripción de un profesional dental autorizado.

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: Rebase duro de prótesis (arco completo) (según proceda)
- Material: Sofreliner (dióxido de silicona)

Fichas de datos de seguridad del material de revestimiento (pasta)
Fichas de datos de seguridad del material del revestimiento (imprimación)

3) Contraindicaciones

No utilizar en pacientes con:

- Hipersensibilidad conocida al material del dispositivo
- Lesiones orales no tratadas

4) Advertencias / Precauciones / Riesgos potenciales

⚠ WARNING

Los riesgos potenciales asociados a los materiales de rebase de prótesis pueden incluir:

- Irritación gingival, dolor de la mucosa, ulceración
- Una adaptación deficiente puede causar inestabilidad o traumatismo
- Respuesta alérgica
- Separación del material

Si el paciente experimenta dolor, irritación u otros efectos adversos, interrumpa el uso y póngase en contacto con el profesional dental responsable del tratamiento.

⚠ CAUTION

NA

5) Limpieza y cuidado

Limpieza diaria:

- Cepille suavemente con un cepillo para prótesis de cerdas suaves o con un cepillo de dientes de cerdas suaves.
- Evite los productos abrasivos (p. ej., pasta de dientes, limpiadores abrasivos, jabones fuertes).
- Utilice jabón lavavajillas líquido suave y no abrasivo, según las indicaciones del profesional dental
- Enjuague bien con agua corriente fría o tibia.
- Evite el calor alto; no use agua caliente o hirviendo.

Remojo:

- Guarde o mantenga en remojo el dispositivo según las indicaciones del profesional dental para evitar que se reseque.
- Evite la inmersión prolongada en limpiadores efervescentes si esto puede dañar el material.

No utilice:

- Evite limpiar/sumergir el dispositivo en productos de hipoclorito de sodio (lejía con cloro), peróxido de hidrógeno, enjuague bucal o alcohol, ya que podrían dañar o decolorar el material.

6) Almacenamiento

Cuando no esté en uso, guarde el dispositivo según las instrucciones del profesional dental. Evite el calor, la presión o las condiciones excesivas que puedan deformar o dañar el dispositivo.

7) Vida esperada / Servicio

Con el cuidado y el mantenimiento adecuados, el dispositivo está diseñado para su uso continuo según las indicaciones del profesional dental. Si el dispositivo se daña o el ajuste deja de ser aceptable, el paciente debe ponerse en contacto con el profesional dental responsable del tratamiento para su evaluación.

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)
- 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

Deseche el dispositivo de acuerdo con la normativa local y los procedimientos del consultorio dental. Si el dispositivo está contaminado con líquidos corporales, trátelo como residuo clínico/infeccioso según los requisitos locales.

UNION EUROPÉENNE (FRANÇAIS)

INSTRUCTIONS D'UTILISATION (IFU)

Union Européenne — Dispositif sur Mesure (CMD)

GMDN / EMDN	Q01020601: Prótesis dentales móviles
Code(s) produit	ACRFDENTRLN, DENTFLRLN, MILLDENTRLN

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)

Ce rebasage de prothèse dentaire sur mesure est destiné à améliorer l'ajustement et la rétention de la prothèse lorsque celle-ci ne s'adapte plus correctement et nécessite un rebasage, conformément à la prescription d'un professionnel dentaire agréé.

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 : Rebasage rigide de prothèse (arcade compl ète), le cas échéant
- Matériel : Sofreliner (dioxyde de silicone)

Fiches de données de sécurité du matériau de rebasage (pâte)
Fiches de données de sécurité du matériau de rebasage (primaire)

3) Contre-indications

Ne pas utiliser chez les patients présentant :

- Hypersensibilité connue au matériau de l'appareil
- Lésions buccodentaires non traitées

4) Avertissements / Précautions / Risques potentiels

⚠ WARNING

Les risques potentiels associés aux matériaux de rebasage des prothèses dentaires peuvent inclure :

- Irritation gingivale, douleurs muqueuses, ulcération
- Une mauvaise adaptation peut provoquer instabilité ou traumatisme
- Réaction allergique
- Séparation des matériaux

Si le patient ressent une douleur, une irritation ou d'autres effets indésirables, il convient d'arrêter l'utilisation et de contacter le dentiste traitant.

⚠ CAUTION

NA

5) Nettoyage et entretien

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

Nettoyage quotidien :

- Nettoyer délicatement à l'aide d'une brosse à dents souple ou d'une brosse à dents souple.
- Éviter les produits abrasifs (p. ex. dentifrice, nettoyants abrasifs, savons forts).
- Utiliser un liquide vaisselle liquide doux et non abrasif selon les instructions du professionnel dentaire.
- Rincer abondamment à l'eau froide ou tiède.
- Éviter les fortes chaleurs ; ne pas utiliser d'eau chaude ou bouillante.

Trempage :

- Stocker/tremper conformément aux instructions du professionnel dentaire afin d'éviter qu'il ne sèche.
- Éviter un trempage prolongé dans les nettoyants effervescents si cela risque d'endommager le matériel.

Ne pas utiliser :

- Éviter de nettoyer/immerger l'appareil dans de l'hypochlorite de sodium (eau de Javel chlorée), du peroxyde d'hydrogène, un bain de bouche ou des produits alcoolisés, car ceux-ci pourraient endommager ou décolorer le matériau.

6) Stockage

Lorsqu'il n'est pas utilisé, stocker l'appareil conformément aux instructions du professionnel dentaire. Éviter toute chaleur excessive, pression ou conditions susceptibles de déformer ou d'endommager l'appareil.

7) Durée de vie / Service attendu

Sous réserve d'un entretien et d'une maintenance appropriés, l'appareil est destiné à une utilisation continue, conformément aux instructions du professionnel dentaire. Si l'appareil est endommagé ou ne s'ajuste plus correctement, le patient doit contacter son dentiste traitant pour qu'il procède à un examen.

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)
- 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

Éliminer l'appareil conformément aux réglementations locales et aux procédures du cabinet dentaire. Si l'appareil est contaminé par des liquides organiques, le traiter comme des déchets cliniques/infectieux conformément aux exigences locales.

EUROPÄISCHE UNION (DEUTSCH)

GEBRAUCHSANWEISUNG (IFU)

EU-SONDERANFERTIGUNG (CMD – Sonderanfertigung)

GMDN / EMDN	Q01020601: Mobile Dental Prostheses
Produktcode(s)	ACRFDENTRLN, DENTFLRLN, MILLDENTRLN

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)

Diese maßgefertigte Prothesenunterfütterung ist dafür bestimmt, den Sitz und den Halt der Prothese zu verbessern, wenn diese nicht mehr wie vorgesehen passt und eine Unterfütterung erforderlich ist, wie von einer zahnärztlichen Fachkraft verordnet.

2) Produktbeschreibung / Hauptspezifikationen

- Maßgefertigte, patientenspezifische Sonderanfertigung, hergestellt nach zahnärztlicher Verordnung und digitalen Eingabedaten.
- Konfiguration: Harte Prothesenunterfütterung (vollständiger Zahnbogen) (falls zutreffend)
- Material: Sofreliner (Siliziumdioxid)

Sicherheitsdatenblätter für Liner (Paste)
Sicherheitsdatenblätter für Liner (Primer)

3) Kontraindikationen

Nicht bei Patienten anwenden, die Folgendes aufweisen:

- Bekannte Überempfindlichkeit gegenüber dem Produktmaterial
- Unbehandelte Läsionen der Mundschleimhaut

4) Warnhinweise / Vorsichtsmaßnahmen / Potenzielle Risiken

⚠ WARNHINWEISE

Zu den möglichen Risiken im Zusammenhang mit Prothesenunterfütterungsmaterialien können Folgende gehören:

- Zahnfleischreizung, Schleimhautentzündung, Ulzeration
- Eine schlechte Passform kann zu Instabilität oder Gewebetraumata führen
- Allergische Reaktion
- Materialablösung

Sollten bei dem Patienten Schmerzen, Reizungen oder andere Nebenwirkungen auftreten, stellen Sie die Anwendung ein und wenden Sie sich an den behandelnden Zahnarzt.

⚠ VORSICHTSMASSNAHMEN

NA

5) Reinigung und Pflege

Tägliche Reinigung:

- Vorsichtig mit einer weichen Prothesenbürste oder einer weichen Zahnbürste abbürsten.
- Scheuernde Produkte (z. B. Zahnpasta, Scheuermittel, starke Reinigungsmittel) vermeiden.
- Verwenden Sie milde, nicht scheuernde Flüssig-Spülseife nach Anweisung der zahnärztlichen Fachkraft.
- Gründlich unter kaltem oder lauwarmem fließendem Wasser abspülen.
- Vermeiden Sie große Hitze; verwenden Sie kein heißes oder kochendes Wasser.
- Einweichen:
- Nach Anweisung der zahnärztlichen Fachkraft lagern oder einweichen, um ein Austrocknen zu verhindern.
- Vermeiden Sie ein längeres Einweichen in Sprudeltabletten-Reinigern, wenn dies das Material beschädigen kann.

Nicht verwenden:

- Vermeiden Sie das Reinigen oder Eintauchen des Produkts in Natriumhypochlorit (Chlorbleiche), Wasserstoffperoxid, Mundspülung oder alkoholhaltige Produkte, da diese das Material beschädigen oder verfärben können.

6) Lagerung

Bewahren Sie die Apparatur bei Nichtverwendung gemäß den Anweisungen der zahnärztlichen Fachkraft auf. Vermeiden Sie übermäßige Hitze, Druck oder Bedingungen, die das Produkt verformen oder beschädigen können.

7) Erwartete Lebensdauer / Nutzungsdauer

Bei entsprechender Pflege und Wartung ist das Produkt für den dauerhaften Einsatz nach Anweisung der zahnärztlichen Fachkraft vorgesehen. Wenn das Gerät beschädigt wird oder nicht mehr passt, sollte der Patient seinen behandelnden Zahnarzt zur Beurteilung kontaktieren.

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

Das Produkt gemäß den örtlichen Vorschriften und den Abläufen der Zahnarztpraxis entsorgen. Wenn das Produkt mit Körperflüssigkeiten kontaminiert ist, ist es gemäß den lokalen Anforderungen als klinischer/infektiöser Abfall zu behandeln.

UNIONE EUROPEA (ITALIANO)

ISTRUZIONI PER L'USO (IFU)

Unione Europea — Dispositivo su Misura (CMD)

GMDN / EMDN	Q01020601: Mobile Dental Prostheses
Codice(i) prodotto	ACRFDENTRLN, DENTFLRLN, MILLDENTRLN

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) Scopo previsto (uso previsto)

Questa ribasatura personalizzata è destinata a migliorare la vestibilità/il trattenimento della protesi quando questa non è più adatta alle esigenze e richiede la rigenerazione, come prescritto da un odontoiatra abilitato.

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: ribasatura per dentiera rigida (arcata intera) (se applicabile)
- Materiale: Sofreliner (biossido di silicone)

Schede di sicurezza del materiale di rivestimento (pasta)
Schede di sicurezza del materiale di rivestimento (primer)

3) Controindicazioni

Non usare in pazienti con:

- Ipersensibilità nota al materiale del dispositivo
- Lesioni orali non trattate

4) Avvertenze / Precauzioni / Rischi potenziali

⚠ AVVERTENZE

I potenziali rischi associati ai materiali di rivestimento della protesi dentaria possono comprendere:
- Irritazione gengivale, dolore alle mucose, ulcerazione
- Uno scarso adattamento può causare instabilità o traumi
- Risposta allergica
- Separazione del materiale

Se il paziente manifesta dolore, irritazione o altri effetti avversi, interrompere l'uso e contattare l'odontoiatra curante.

⚠ PRECAUZIONI

NA

5) Pulizia e cura

Pulizia giornaliera:
- Spazzolare delicatamente usando uno spazzolino per dentiere a setole morbide o uno spazzolino da denti morbido.
- Evitare prodotti abrasivi (es. dentifricio, detergenti abrasivi, saponi aggressivi).
- Utilizzare detersivo per piatti liquido delicato e non abrasivo, come indicato dall'odontoiatra
- Sciacquare accuratamente con acqua corrente fredda o tiepida.
- Evitare il calore elevato; non utilizzare acqua calda o bollente.
- Immersione:
- Conservare/immergere come indicato dall'odontoiatra per evitare l'asciugatura.
- Evitare immersioni prolungate in detergenti effervescenti se possono danneggiare il materiale.

Non utilizzare:
- Evitare di pulire/immergere il dispositivo in ipoclorito di sodio (candeggina), perossido di idrogeno, collutorio o prodotti contenenti alcol, in quanto potrebbero danneggiare o scolorire il materiale.

6) Conservazione

Quando non in uso, conservare il dispositivo come indicato dall'odontoiatra. Evitare calore, pressione o condizioni eccessive che possono deformare o danneggiare il dispositivo.

7) Durata prevista / Servizio

Con un'adeguata cura e manutenzione, il dispositivo è destinato all'uso continuato secondo le indicazioni dell'odontoiatra. Se il dispositivo si danneggia o non è più idoneo, il paziente deve contattare il proprio odontoiatra per la valutazione.

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

Smaltire il dispositivo in conformità alle normative locali e alle procedure dello studio dentistico. Se il dispositivo è contaminato da liquidi corporei, trattarlo come rifiuto clinico/infettivo secondo i requisiti locali.

UNITED KINGDOM (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

United Kingdom — Custom-Made Device (CMD)

GMDN / EMDN	17609
Product Code(s)	ACRFDENTRLN, DENTFLRLN, MILLDENTRLN

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 (if applicable)
Single-use / Reusable	Reusable

1) Intended Purpose (Intended Use)

This custom-made denture reliner is intended to improve denture fit/retention when a denture no longer fits as intended and requires relining, as prescribed by a licensed dental professional.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Hard denture reline (full arch) (as applicable)
- Material: Sofreliner (Silicone Dioxide)

Liner Material Safety Data Sheets (Paste)
Liner Material Safety Data Sheets (Primer)

3) Contraindications

Do not use in patients with:

- Known hypersensitivity to the device material
- Untreated oral lesions

4) Warnings / Precautions / Potential Risks

⚠ WARNING

Potential risks associated with denture lining materials may include:

- Gingival irritation, mucosal soreness, ulceration
- Poor adaptation may cause instability or trauma
- Allergic response
- Separation of material

If the patient experiences pain, irritation, or other adverse effects, discontinue use and contact the treating dental professional.

⚠ CAUTION

NA

5) Cleaning and Care

Daily cleaning:

- Brush gently using a soft-bristled denture brush or soft toothbrush.
- Avoid abrasive products (e.g., toothpaste, abrasive cleaners, strong soaps).
- Use mild, non-abrasive liquid dish soap as directed by the dental professional.
- Rinse thoroughly under cool or lukewarm running water.
- Avoid high heat; do not use hot or boiling water.

Soaking:

- Store/soak as directed by the dental professional to prevent drying.
- Avoid prolonged soaking in effervescent cleaners if this may damage the material.

Do not use:

- Avoid cleaning/immersing the device in sodium hypochlorite (chlorine bleach), hydrogen peroxide, mouthwash, or alcohol products, as these may damage or discolour the material.

6) Storage

When not in use, store the device as directed by the dental professional. Avoid excessive heat, pressure, or conditions that may deform or damage the device.

7) Expected Life / Service

With appropriate care and maintenance, the device is intended for ongoing use as directed by the dental professional. If the device becomes damaged or fit is no longer acceptable, the patient should contact their treating dental professional for evaluation.

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

Dispose of the device in accordance with local regulations and the dental practice's procedures. If the device is contaminated with bodily fluids, treat it as clinical/infectious waste per local requirements.

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	12-Jun-2026 01:43

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