



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	Inlay - Metal
GMDN / EMDN Code	38648
Product Code(s)	GLDHNSINA, GLDHNSINP, GLDNPSINP, GLDNWSINP, GLDNYSINP
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	38648
Product Code(s)	GLDHNSINA, GLDHNSINP, GLDNPSINP, GLDNWSINP, GLDNYSINP
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)

Dandy's Inlay/Onlay restorations are designed to restore worn, decayed, or broken dentition.

They:

Restore single, permanent teeth that are fractured, carious, or severely worn.

Restore the form and function of natural dentition.

Provide occlusal stability and maintain proper interarch relationships.

More conservative preparation, compared to Crowns and Bridges.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Dandy's restorations are fabricated using digital technology, enabling a precise fit and customization tailored to the patient's specific needs. They are made of a highly durable and biocompatible material, ensuring long-term comfort and function.
- Material: High-Noble: Rich Yellow (ArgenMill Au58), Noble White (ArgencoW), Non-Precious (ArgenMillCoCr)

[Full Metal Material Safety Data Sheets](#)

3) Contraindications

Inlays/Onlays should be used with caution in patients with uncontrolled periodontal disease, severe bone resorption, or oral lesions.

4) Warnings / Precautions / Potential Risks

WARNING

The use of fixed restorations may have potential risks, including failure, misfit, breakage, and recurrent caries.

****Warning – Sensitivity:**

This device contains a level of metal (including nickel). Patients with sensitivity or allergy to metals should be informed by the treating clinician of the presence of these compounds in the device prior to treatment. In rare cases, allergic reactions may occur in sensitized individuals.

***Warning – Irritation:**

Localized irritation of surrounding oral tissues may occur in certain individuals due to individual variability in tissue response. Patients should be monitored post-placement, and the treating clinician should evaluate any signs of irritation, inflammation, or discomfort.

CAUTION

na

5) Cleaning and Care

Daily Cleaning

- Oral Hygiene:
 - Brushing:
 - Recommended brushing teeth twice a day, using a soft-bristled toothbrush and a fluoride toothpaste.
 - Flossing:
 - Recommend daily flossing to remove plaque and debris from between the teeth and around the fixed restoration. A floss threader may be needed for hard-to-reach areas.
 - Mouthwash:
 - Alcohol-based mouthwashes tend to dry out the mouth and lead to increased plaque and tartar buildup.

Dietary and Habit Recommendations

- Avoid abrasive foods: Limit hard, crunchy, or sticky foods that can damage the restoration or cause it to loosen.
- Avoid sugary foods: where new cavities can form or cause premature decay of the restorative margins.
- Stay hydrated: Drinking plenty of water will help keep your patient's mouth clean and prevent gum disease.
- Avoid bad habits: Refrain from using teeth to open packages or biting on hard objects

6) Storage

Stored in specialized boxes with foam or membranes for protection, often made of ABS plastic. For patients who lose a crown, store it in a sealed bag or a small container with a small amount of water to keep it safe and moist until the dentist's visit.

7) Expected Life / Service

They offer exceptional longevity, typically lasting 20 years or more, often extending to 30 years or even a lifetime with excellent care, thanks to their unmatched durability, resistance to chipping, and precise fit.

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

- Dandy asks that restorations that contain precious metals created by Dandy that need refabrication, be returned to us.
- Disposing of metal dental restorations involves either recycling them as precious metals (especially if gold alloy) through specialized refineries or scrap dealers for value, or general recycling if non-precious (like steel), but never in regular trash.
 - Precious Metal Refining: Many dental restorations contain valuable metals, making them a valuable asset for recycling.
 - Specialized Refiners: Some companies offer mail-in programs where you send in your scrap in prepaid, insured envelopes for assay and payment.
- How it Works: You send your restorations, they refine the metals, and pay you based on current market prices, often with insured shipping.
- For Non-Precious Metal Restorations
 - Dandy restorations that need refabrication, do not have to be returned to us.
 - Scrap Metal Dealers: various scrap metals, offering pickup or drop-off, though you'd need to confirm if they take small dental items.
 - General Recycling: Check with your local sanitation department for guidelines on disposing of bulk or metal items if it's not a dental office scenario.

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

European Union — Custom-Made Device (CMD)

GMDN / EMDN	Q010206 - Dental Prostheses
Product Code(s)	GLDHNSINA, GLDHNSINP, GLDNPSINP, GLDNWSINP, GLDNYSINP
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)

Dandy's Inlay/Onlay restorations are designed to restore worn, decayed, or broken dentition.

They:

- Restore single, permanent teeth that are fractured, carious, or severely worn.
- Restore the form and function of natural dentition.
- Provide occlusal stability and maintain proper interarch relationships.
- More conservative preparation, compared to Crowns and Bridges.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Dandy's restorations are fabricated using digital technology, enabling a precise fit and customization tailored to the patient's specific needs. They are made of a highly durable and biocompatible material, ensuring long-term comfort and function.
- Material: High-Noble: Rich Yellow (ArgenMill Au58), Noble White (ArgencoW), Non-Precious (ArgenMillCoCr)

[Full Metal Material Safety Data Sheets](#)

3) Contraindications

Inlays/Onlays should be used with caution in patients with uncontrolled periodontal disease, severe bone resorption, or oral lesions.

4) Warnings / Precautions / Potential Risks

WARNING

The use of fixed restorations may have potential risks, including failure, misfit, breakage, and recurrent caries.

****Warning – Sensitivity:**

This device contains a level of metal (including nickel). Patients with sensitivity or allergy to metals should be informed by the treating clinician of the presence of these compounds in the device prior to treatment. In rare cases, allergic reactions may occur in sensitized individuals.

***Warning – Irritation:**

Localized irritation of surrounding oral tissues may occur in certain individuals due to individual variability in tissue response. Patients should be monitored post-placement, and the treating clinician should evaluate any signs of irritation, inflammation, or discomfort.

CAUTION

na

5) Cleaning and Care

Daily Cleaning

- Oral Hygiene:
 - Brushing:
 - Recommended brushing teeth twice a day, using a soft-bristled toothbrush and a fluoride toothpaste.
 - Flossing:
 - Recommend daily flossing to remove plaque and debris from between the teeth and around the fixed restoration. A floss threader may be needed for hard-to-reach areas.
 - Mouthwash:
 - Alcohol-based mouthwashes tend to dry out the mouth and lead to increased plaque and tartar buildup.

Dietary and Habit Recommendations

- Avoid abrasive foods: Limit hard, crunchy, or sticky foods that can damage the restoration or cause it to loosen.
- Avoid sugary foods: where new cavities can form or cause premature decay of the restorative margins.
- Stay hydrated: Drinking plenty of water will help keep your patient's mouth clean and prevent gum disease.
- Avoid bad habits: Refrain from using teeth to open packages or biting on hard objects

6) Storage

Stored in specialized boxes with foam or membranes for protection, often made of ABS plastic. For patients who lose a crown, store it in a sealed bag or a small container with a small amount of water to keep it safe and moist until the dentist's visit.

7) Expected Life / Service

They offer exceptional longevity, typically lasting 20 years or more, often extending to 30 years or even a lifetime with excellent care, thanks to their unmatched durability, resistance to chipping, and precise fit.

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

- Dandy asks that restorations that contain precious metals created by Dandy that need refabrication, be returned to us.
- Disposing of metal dental restorations involves either recycling them as precious metals (especially if gold alloy) through specialized refineries or scrap dealers for value, or general recycling if non-precious (like steel), but never in regular trash.
 - Precious Metal Refining: Many dental restorations contain valuable metals, making them a valuable asset for recycling.
 - Specialized Refiners: Some companies offer mail-in programs where you send in your scrap in prepaid, insured envelopes for assay and payment.
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 - General Recycling: Check with your local sanitation department for guidelines on disposing of bulk or metal items if it's not a dental office scenario.



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

Unión Europea — Producto Sanitario a Medida (CMD)

GMDN / EMDN	Q010206 - Prótesis dentales
Código(s) del producto	GLDHNSINA, GLDHNSINP, GLDNPSINP, GLDNWSINP, GLDNYSINP
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)

Las restauraciones tipo inlay/onlay de Dandy están diseñadas para restaurar dentición desgastada, cariada o fracturada.

Los puentes:

- Restauran dientes permanentes individuales que presentan fracturas, caries o desgaste intenso.
- Restauran la forma y la función de la dentición natural.
- Proporcionan estabilidad oclusal y mantienen unas relaciones interarcales adecuadas.
- Preparación más conservadora en comparación con coronas y puentes.

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: Las restauraciones de Dandy se fabrican mediante tecnología digital, lo que permite un ajuste preciso y una personalización adaptada a las necesidades específicas del paciente. Están fabricados con un material altamente duradero y biocompatible, lo que garantiza confort y funcionalidad a largo plazo.
- Material: Aleación de alto contenido noble: Amarillo intenso (ArgenMill Au58), blanco noble (ArgencoW), no precioso (ArgenMillCoCr)

[Fichas de datos de seguridad de materiales para metal completo](#)

3) Contraindicaciones

Las incrustaciones inlay/onlay deben utilizarse con precaución en pacientes con enfermedad periodontal no controlada, reabsorción ósea severa o lesiones orales.

4) Advertencias / Precauciones / Riesgos potenciales

ADVERTENCIAS

El uso de restauraciones fijas puede conllevar riesgos potenciales, como fracaso, desajuste, fractura y caries recurrente.

****Advertencia – Sensibilidad:**

Este dispositivo contiene metal, incluido níquel. Los pacientes con sensibilidad o alergia a los metales deben ser informados por el facultativo responsable del tratamiento de la presencia de estos compuestos en el dispositivo antes del tratamiento. En casos raros, pueden producirse reacciones alérgicas en individuos sensibilizados.

***Advertencia – Irritación:**

En determinadas personas puede producirse irritación localizada de los tejidos orales circundantes debido a la variabilidad individual en la respuesta tisular. Debe supervisarse a los pacientes después de la colocación, y el médico responsable del tratamiento debe evaluar cualquier signo de irritación, inflamación o malestar.

CAUTION

NA

5) Limpieza y cuidado

Limpieza diaria

- Higiene bucal:
 - Cepillado:
 - Se recomienda cepillarse los dientes dos veces al día con un cepillo de cerdas suaves y un dentífrico fluorado.
 - Uso de hilo dental:
 - Recomiende el uso diario de hilo dental para eliminar la placa y los restos entre los dientes y alrededor de la restauración fija. Puede ser necesario utilizar un enhebrador de hilo dental en zonas de difícil acceso.
 - Enjuague bucal:
 - Los enjuagues bucales a base de alcohol tienden a secar la boca y a aumentar la acumulación de placa y sarro.

Recomendaciones alimentarias y de hábitos

- Evite los alimentos abrasivos: Limite los alimentos duros, crujientes o pegajosos que puedan dañar la restauración o hacer que se afloje.
- Evite los alimentos azucarados: ya que pueden favorecer la aparición de nuevas caries o el deterioro prematuro de los márgenes de la restauración.
- Manténgase hidratado/a: Beber abundante agua ayudará a mantener limpia la boca del paciente y a prevenir la enfermedad periodontal.
- Evite los malos hábitos: Absténgase de usar sus dientes para abrir envases o morder objetos duros.

6) Almacenamiento

Debe almacenarse en estuches especializados con espuma o membranas de protección, a menudo fabricados en plástico ABS. En el caso de pacientes que pierdan una corona, guárdela en una bolsa sellada o en un pequeño recipiente con una pequeña cantidad de agua para mantenerla segura y húmeda hasta la visita al dentista.

7) Vida esperada / Servicio

Ofrecen una longevidad excepcional, normalmente de 20 años o más, y a menudo pueden alcanzar los 30 años o incluso durar toda la vida con unos cuidados excelentes, gracias a su durabilidad inigualable, su resistencia al astillado y su ajuste preciso.

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

- Dandy solicita que las restauraciones fabricadas por Dandy que contengan metales preciosos y requieran refabricación nos sean devueltas.
- La eliminación de restauraciones dentales metálicas implica reciclarlas como metales preciosos (especialmente si contienen aleaciones de oro) a través de refinerías especializadas o chatarreros autorizados, o bien reciclarlas como metal convencional si no son preciosas (como el acero), pero nunca desecharlas en la basura convencional.
 - Refinado de metales preciosos: Muchas restauraciones dentales contienen metales valiosos, lo que las convierte en un material de interés para el reciclaje.
 - Refinadores especializados: Algunas empresas ofrecen programas de envío por correo en los que usted remite sus restos en sobres prepagados y asegurados para su valoración y posterior pago.
- Cómo funciona: Usted envía sus restauraciones, la empresa refina los metales y le paga según los precios actuales del mercado, a menudo con envío asegurado.
- Para las restauraciones de metales no preciosos
 - Las restauraciones de Dandy que necesiten refabricación no tienen que devolverse.
 - Chatarreros autorizados: diversos tipos de chatarra metálica, con opciones de recogida o entrega, aunque deberá confirmar si aceptan pequeñas piezas dentales.



- Reciclaje general: Consulte con el servicio municipal correspondiente las directrices para la eliminación de objetos metálicos o de gran volumen si no se trata de un entorno de clínica dental.

UNION EUROPÉENNE (FRANÇAIS)

INSTRUCTIONS D'UTILISATION (IFU)

Union Européenne — Dispositif sur Mesure (CMD)

GMDN / EMDN	Q010206 - Prothèses dentaires
Code(s) produit	GLDHNSINA, GLDHNSINP, GLDNPSINP, GLDNWSINP, GLDNYSINP
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 (le cas échéant)
Usage unique / Réutilisable	Réutilisable

1) Usage prévu (utilisation prévue)

Les restaurations inlay/onlay de Dandy sont conçues pour restaurer les dents usées, cariées ou cassées.

Ils :

Restaurer des dents individuelles permanentes fracturées, cariées ou fortement usées.

Restaurer la forme et la fonction de la dentition naturelle.

Assurent la stabilité occlusale et préservent les relations interarcades correctes.

Une préparation moins invasive que celle requise pour les couronnes et les bridges.

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 restaurations Dandy sont fabriquées à l'aide de technologies numériques, ce qui garantit un ajustement précis et une personnalisation adaptée aux besoins spécifiques du patient. Ils sont fabriqués à partir d'un matériau hautement durable et biocompatible, assurant confort et fonctionnalité à long terme.
- Matériel : Très noble : Jaune intense (ArgenMi II Au58), Blanc noble (ArgencoW), Métal non précieux (ArgenMill CoCr)

[Fiches de données de sécurité des matériaux entièrement métalliques](#)

3) Contre-indications

Les inlays/onlays doivent être utilisés avec prudence chez les patients présentant une maladie parodontale non contrôlée, une résorption osseuse sévère ou des lésions buccodentaires.

4) Avertissements / Précautions / Risques potentiels

⚠ Avertissements

L'utilisation de restaurations fixes peut présenter des risques potentiels, notamment une défaillance, un mauvais ajustement, une rupture et des caries récurrentes.

****Avertissement – Sensibilité :**

Cet appareil contient des métaux (dont du nickel). Les patients sensibles ou allergiques aux métaux doivent être informés par le clinicien traitant de la présence de ces composés dans l'appareil avant le traitement. Dans de rares cas, des réactions allergiques peuvent survenir chez les personnes sensibilisées.

***Avertissement – Irritation :**

Une irritation localisée des tissus buccaux environnants peut survenir chez certains individus en raison de la variabilité individuelle de la réponse tissulaire. Les patients doivent être surveillés après la mise en place et le médecin traitant doit évaluer tout signe d'irritation, d'inflammation ou d'inconfort.

⚠ CAUTION

NA

5) Nettoyage et entretien

Nettoyage quotidien

- Hygiène buccodentaire :
 - Brossage :
 - Il est recommandé de se brosser les dents deux fois par jour, à l'aide d'une brosse à dents à poils souples et d'un dentifrice fluoré.
 - Utilisation du fil dentaire :
 - Recommander une utilisation quotidienne du fil dentaire pour éliminer la plaque dentaire et les résidus alimentaires entre les dents et autour de la restauration fixe. Un enfile-fil dentaire peut s'avérer nécessaire pour les zones difficiles d'accès.
 - Bain de bouche :
 - Les bains de bouche à base d'alcool ont tendance à dessécher la bouche et entraînent une augmentation de la plaque dentaire et de l'accumulation de tartre.

Recommandations alimentaires et habitudes

- Éviter les aliments abrasifs : Limiter la consommation d'aliments durs, croquants ou collants qui pourraient endommager la restauration ou la faire se desceller.
- Éviter les aliments sucrés : Où de nouvelles cavités peuvent former ou provoquer une dégradation prématurée des marges de restauration.
- Rester hydraté : Boire beaucoup d'eau aidera à garder la bouche de votre patient propre et à prévenir les maladies des gencives.
- Éviter les mauvaises habitudes : Ne pas utiliser les dents pour ouvrir des emballages ou mordre sur des objets durs.

6) Stockage

Conditionné dans des boîtes spécialisées, avec de la mousse ou des membranes de protection, souvent en plastique ABS. Pour les patients qui perdent une couronne, la conserver dans un sac scellé ou un petit contenant avec une petite quantité d'eau pour la garder en sécurité et humide jusqu'à la visite du dentiste.

7) Durée de vie / Service attendu

Ils offrent une longévité exceptionnelle, avec une durée de vie généralement de 20 ans ou plus, pouvant souvent atteindre 30 ans, voire durer toute une vie s'ils sont bien entretenus, grâce à leur durabilité inégalée, leur résistance aux éclats et leur ajustement précis.

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

- Dandy demande que les restaurations contenant des métaux précieux réalisées par Dandy et nécessitant une refabrication nous soient renvoyées.
- Pour éliminer les restaurations dentaires métalliques, il faut soit les recycler en tant que métaux précieux (notamment s'il s'agit d'alliages d'or) auprès de raffineries spécialisées ou de ferrailleurs afin d'en tirer une valeur, soit les recycler de manière classique s'il s'agit de métaux non précieux (comme l'acier), mais en aucun cas les jeter avec les ordures ménagères.
 - Raffinage des métaux précieux : De nombreuses restaurations dentaires contiennent des métaux précieux, ce qui en fait un atout précieux pour le recyclage.
 - Raffineurs spécialisés : Certaines entreprises proposent des programmes par correspondance dans le cadre desquels vous envoyez vos déchets dans des

enveloppes préaffranchies et assurées afin qu'ils soient analysés et que vous soyez payé.

- Fonctionnement : Vous envoyez vos restaurations, elles affinent les métaux, et vous payent sur la base des prix actuels du marché, souvent avec une livraison assurée.
- Pour les restaurations en métaux non précieux
 - Les restaurations Dandy qui doivent être refabriquées ne doivent pas nous être retournées.
 - Ferrailleurs : divers déchets métalliques ; ils proposent un service d'enlèvement ou de dépôt, mais il faudrait vérifier s'ils acceptent les petits objets dentaires.
 - Recyclage général : Si vous n'êtes pas dans le cadre d'un cabinet dentaire, vérifier auprès de votre service municipal chargé de l'assainissement les consignes relatives à l'élimination des déchets volumineux ou des objets métalliques.

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

EU-SONDERANFERTIGUNG (CMD – Sonderanfertigung)

GMDN / EMDN	Q010206 – Zahnprothesen
Produktcode(s)	GLDHNSINA, GLDHNSINP, GLDNPSINP, GLDNWSINP, GLDNYSINP
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:	Einmalgebrauch

1) Zweckbestimmung (Verwendungszweck)

- Dandy Inlay/Onlay-Restaurationen sind dafür bestimmt, abgenutzte, kariöse oder abgebrochene Zähne wiederherzustellen.
- Sie:
 - Zur Wiederherstellung einzelner, bleibender Zähne, die frakturiert, kariös oder stark abgenutzt sind.
 - Zur Wiederherstellung von Form und Funktion des natürlichen Gebisses.
 - Gewährleisten okklusale Stabilität und erhalten die korrekte Kieferrelation.
 - Konservativere Präparation im Vergleich zu Kronen und Brücken.

2) Produktbeschreibung / Hauptspezifikationen

- Maßgefertigte, patientenspezifische Sonderanfertigung, hergestellt nach zahnärztlicher Verordnung und digitalen Eingabedaten.
- Konfiguration: Die Versorgungen von Dandy werden unter Einsatz digitaler Technologien gefertigt, was eine präzise Passform sowie eine exakt auf die spezifischen Bedürfnisse des Patienten abgestimmte Individualisierung ermöglicht. Sie bestehen aus einem hochgradig langlebigen und biokompatiblen Material, was langfristigen Komfort und uneingeschränkte Funktion gewährleistet.
- Material: Hochedelmetallhaltig: Sattingelb/Hochgold (ArgenMill Au58), Weißgold (ArgencoW), Nichtedelmetall (ArgenMillCoCr)

[Sicherheitsdatenblätter für Metall](#)

3) Kontraindikationen

Inlays/Onlays sollten bei Patienten mit unkontrollierter Parodontalerkrankung, schwerer Knochenresorption oder Läsionen der Mundschleimhaut nur mit Vorsicht angewendet werden.

4) Warnhinweise / Vorsichtsmaßnahmen / Potenzielle Risiken

⚠️ WARNHINWEISE

Die Verwendung von feststehendem Zahnersatz birgt potenzielle Risiken, einschließlich Versagen, Passungenauigkeit, Bruch und Sekundärkaries.

****Warnhinweis – Empfindlichkeit:**

- Dieses Produkt enthält einen Anteil an Metall (einschließlich Nickel). Patienten mit einer Überempfindlichkeit oder Allergie gegen Metalle müssen vor der Behandlung vom behandelnden Arzt über das Vorhandensein dieser Stoffe im Produkt informiert werden. In seltenen Fällen können bei sensibilisierten Personen ggf. allergische Reaktionen auftreten.

***Warnhinweis – Reizung:**

- Aufgrund der individuellen Variabilität der Gewebereaktion kann es bei bestimmten Personen zu lokalen Irritationen des umgebenden oralen Gewebes kommen. Die Patienten sollten nach dem Einsetzen überwacht werden, und der behandelnde Arzt sollte jegliche Anzeichen von Reizung, Entzündung oder Missempfinden evaluieren.

⚠️ VORSICHTSMASSNAHMEN

NA

5) Reinigung und Pflege

Tägliche Reinigung

- Mundhygiene:
 - Zähneputzen:
 - Empfohlen wird zweimal tägliches Zähneputzen mit einer weichen Zahnbürste und einer fluoridhaltigen Zahnpasta.
 - Zahnseide:
 - Es wird eine tägliche Anwendung von Zahnseide empfohlen, um Plaque und Speisereste aus den Zahnzwischenräumen sowie im Bereich des feststehenden Zahnersatzes zu entfernen. Für schwer zugängliche Bereiche kann eine Einfädelhilfe für Zahnseide erforderlich sein.
 - Mundspülung:
 - Alkoholhaltige Mundspülungen neigen dazu, den Mund auszutrocknen, was zu einer verstärkten Bildung von Plaque und Zahnstein führt.

Empfehlungen zu Ernährung und Gewohnheiten

- Vermeidung abrasiver Lebensmittel: Vermeiden Sie nach Möglichkeit harte, knusprige oder klebrige Speisen. Diese können die Restauration beschädigen oder dazu führen, dass sie sich lockert.
- Vermeidung zuckerhaltiger Lebensmittel: Diese begünstigen die Entstehung von neuer Karies und können zu einem vorzeitigen Abbau der Kronen- und Brückenränder führen.
- Hydriert bleiben: Das Trinken von reichlich Wasser trägt dazu bei, die Mundhöhle des Patienten sauber zu halten und Parodontalerkrankungen vorzubeugen.
- Vermeidung schlechter Gewohnheiten: Verzicht auf das Öffnen von Verpackungen oder zum Beißen auf harte Gegenstände zu verwenden.

6) Lagerung

Die Lagerung erfolgt in speziellen Boxen mit Schaumstoff- oder Membraneinsätzen zum Schutz, häufig hergestellt aus ABS-Kunststoff. Patienten, die eine Krone verlieren, sollte diese in einem versiegelten Beutel oder einem kleinen Behälter mit etwas Wasser aufbewahren, um sie bis zum Zahnarztbesuch geschützt und feucht zu halten.

7) Erwartete Lebensdauer / Zeit der Benutzung

Sie zeichnen sich durch eine herausragende Haltbarkeit von meist über 20 Jahren aus. Bei optimaler Pflege können sie dank ihrer enormen Robustheit, extremen Bruchsicherheit und exakten Passung oft 30 Jahre oder ein Leben lang im Mund verbleiben.

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

- Dandy bittet darum, von Dandy gefertigte Restaurationen, die Edelmetalle enthalten und neu angefertigt werden müssen, an uns zurückzusenden.
- Die Entsorgung von metallischem Zahnersatz erfolgt entweder durch das Recycling als Edelmetall (insbesondere bei Goldlegierungen) über spezialisierte Scheideanstalten oder Altmetallhändler zur Wertstoffrückgewinnung, oder über das allgemeine Metallrecycling bei Nichtedelmetallen (wie Stahl), jedoch niemals über den normalen Hausmüll.
 - Edelmetallrückgewinnung: Viele zahnmedizinische Restaurationen enthalten wertvolle Metalle, was sie zu einem wertvollen Gut für das Recycling macht.
 - Spezialisierte Scheideanstalten: Einige Unternehmen bieten Post-Einsende-Programme an, bei denen Sie Ihr Altmetall in vorfrankierten, versicherten Umschlägen zur Analyse und Vergütung einsenden können.

- So funktioniert es: Sie senden Ihre Restaurationen ein, das Unternehmen raffiniert die Metalle und vergütet Sie auf Basis der aktuellen Marktpreise, häufig inklusive versichertem Versand.
 - Für Nichtedelmetall-Restaurationen
 - Von Dandy gefertigte Restaurationen, die eine Neuanfertigung erfordern, müssen nicht an uns zurückgesendet werden.
 - Altmetallhändler: Verschiedene Altmetalle mit Option der Abholung oder Selbstanlieferung, wobei vorab zu klären ist, ob auch zahnmedizinische Kleinteile angenommen werden.
- Allgemeines Recycling: Informieren Sie sich bei Ihrer zuständigen kommunalen Abfallwirtschaft über die Richtlinien für die Entsorgung von Sperrmüll oder Metallgegenständen, wenn es sich nicht um Abfälle einer zahnmedizinischen Praxis handelt.

UNIONE EUROPEA (ITALIANO)

ISTRUZIONI PER L'USO (IFU)

DISPOSITIVO PERSONALIZZATO UE (CMD = Dispositivo personalizzato)

GMDN / EMDN	Q010206 – Protesi dentarie
Codice(i) prodotto	GLDHNSINA, GLDHNSINP, GLDNPSINP, GLDNWSINP, GLDNYSINP

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)

- I restauri inlay/onlay di Dandy sono progettati per ripristinare denti usurati, cariati o fratturati.
- Questi dispositivi:
 - Restaurano denti singoli e permanenti fratturati, cariati o gravemente usurati.
 - Ripristinano la forma e la funzione della dentatura naturale.
 - Forniscono stabilità occlusale e mantengono le corrette relazioni tra le arcate.
 - Preparazione più conservativa, rispetto a corone e ponti.

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 restauri di Dandy sono realizzati utilizzando la tecnologia digitale, consentendo una precisa vestibilità e personalizzazione su misura in base alle esigenze specifiche del paziente. Sono realizzati in materiale altamente resistente e biocompatibile, garantendo comfort e funzionalità a lungo termine.
- Materiale: alta percentuale di nobili: giallo ricco (ArgenMill Au58), bianco nobile (ArgencoW), non prezioso (ArgenMillCoCr).

[Schede di sicurezza del materiale di metallo completo](#)

3) Controindicazioni

Gli inlay/onlay devono essere utilizzati con cautela in pazienti con malattia parodontale non controllata, grave riassorbimento osseo o lesioni orali.

4) Avvertenze / Precauzioni / Rischi potenziali

AVVERTENZE

L'uso di restauri fissi può comportare rischi potenziali, tra cui lesioni, malformazioni, rotture e carie ricorrenti.

****Avvertenza – Sensibilità:**

- Questo dispositivo contiene metalli (compreso il nichel). Prima del trattamento, i pazienti con sensibilità o allergia ai metalli devono essere informati dal medico curante della presenza di questi composti nel dispositivo. In rari casi, si possono verificare reazioni allergiche in individui sensibilizzati.

***Avvertenza – Irritazione:**

- In alcuni individui può verificarsi irritazione localizzata dei tessuti orali circostanti a causa della variabilità individuale della risposta tissutale. I pazienti devono essere monitorati dopo il posizionamento e il medico curante deve valutare eventuali segni di irritazione, infiammazione o fastidio.

PRECAUZIONI

NA

5) Pulizia e cura

Pulizia quotidiana

- Igiene orale:
 - Spazzolamento:
 - Si raccomanda di lavarsi i denti due volte al giorno, utilizzando uno spazzolino da denti a setole morbide e un dentifricio al fluoro.
 - Filo interdentale:
 - Si consiglia di utilizzare ogni giorno il filo interdentale per rimuovere la placca e i detriti tra i denti e intorno al restauro fisso. Può essere necessario una punta passafilo per le aree difficili da raggiungere.
 - Collutorio:
 - I collutori contenenti alcol tendono ad asciugare la bocca, con conseguente aumento della formazione di placca e tartaro.

Consigli sull'alimentazione e sulle abitudini

- Evitare alimenti abrasivi: limitare il consumo di cibi duri, croccanti o appiccicosi che possono danneggiare il restauro o causarne l'allentamento.
- Evitare i cibi zuccherati: laddove possono formarsi nuove cavità o causano un decadimento prematuro dei margini di restauro.
- Rimanere idratati: bere molta acqua aiuterà a mantenere pulita la bocca del paziente e a prevenire le malattie gengivali.
- Evitare cattive abitudini: evitare di usare i denti per aprire pacchetti o mordere oggetti duri.

6) Conservazione

Conservato in scatole dedicate con schiuma o membrane per la protezione, spesso realizzate in plastica ABS. Per i pazienti che perdono una corona, conservarla in un sacchetto sigillato o in un piccolo contenitore con una piccola quantità di acqua per mantenerla sicura e umida fino alla visita dal dentista.

7) Durata prevista / Servizio

Offrono una longevità eccezionale, di solito 20 anni o più, che spesso si estende fino a 30 anni o anche per tutta la vita praticando una cura eccellente, grazie alla loro resistenza senza pari, anti-scheggiatura e vestibilità precisa.

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

- Dandy chiede la restituzione dei restauri che contengono metalli preziosi creati da Dandy che necessitano di rigenerazione.
- Lo smaltimento dei restauri dentali in metallo comporta il loro riciclaggio come metalli preziosi (specialmente se in lega d'oro) attraverso raffinerie specializzate o rivenditori di rottami per valore, o il riciclaggio generale se non preziosi (come l'acciaio), ma mai tra i rifiuti normali.
 - Raffinazione di metalli preziosi: molti restauri dentali contengono metalli preziosi, il che li rende un bene prezioso per il riciclaggio.
 - Raffinatori specializzati: alcune aziende offrono programmi di scambio per corrispondenza in cui si spediscono i pezzi in buste prepagate e assicurate per analisi e pagamento.
- Come funziona: il dentista invia i restauri, l'azienda raffina i metalli e paga il dentista in base agli attuali prezzi di mercato, spesso con una spedizione assicurata.
- Per i restauri in metallo non prezioso
 - I restauri di Dandy che necessitano di rigenerazione, non devono essere restituiti a noi.
 - Rivenditori di rottami metallici: vari metalli di scarto, con prelievo o consegna, anche se sarebbe necessario confermare se prendono piccoli oggetti dentali.
 - Riciclaggio generale: verificare con l'azienda di raccolta rifiuti locale le linee guida sullo smaltimento di articoli sfusi o in metallo se non si tratta di uno scenario per gli ambulatori dentistici.

UNITED KINGDOM (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

United Kingdom — Custom-Made Device (CMD)

GMDN / EMDN	38648
Product Code(s)	GLDHNSINA, GLDHNSINP, GLDNPSINP, GLDNWSINP, GLDNYSINP
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)

Dandy's Inlay/Onlay restorations are designed to restore worn, decayed, or broken dentition.

They:

- Restore single, permanent teeth that are fractured, carious, or severely worn.
- Restore the form and function of natural dentition.
- Provide occlusal stability and maintain proper interarch relationships.
- More conservative preparation, compared to Crowns and Bridges.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Dandy's restorations are fabricated using digital technology, enabling a precise fit and customization tailored to the patient's specific needs. They are made of a highly durable and biocompatible material, ensuring long-term comfort and function.
- Material: High-Noble: Rich Yellow (ArgenMill Au58), Noble White (ArgencoW), Non-Precious (ArgenMillCoCr)

[Full Metal Material Safety Data Sheets](#)

3) Contraindications

Inlays/Onlays should be used with caution in patients with uncontrolled periodontal disease, severe bone resorption, or oral lesions.

4) Warnings / Precautions / Potential Risks

WARNING

The use of fixed restorations may have potential risks, including failure, misfit, breakage, and recurrent caries.

****Warning – Sensitivity:**

This device contains a level of metal (including nickel). Patients with sensitivity or allergy to metals should be informed by the treating clinician of the presence of these compounds in the device prior to treatment. In rare cases, allergic reactions may occur in sensitized individuals.

***Warning – Irritation:**

Localized irritation of surrounding oral tissues may occur in certain individuals due to individual variability in tissue response. Patients should be monitored post-placement, and the treating clinician should evaluate any signs of irritation, inflammation, or discomfort.

CAUTION

na

5) Cleaning and Care

Daily Cleaning

- Oral Hygiene:
 - Brushing:
 - Recommended brushing teeth twice a day, using a soft-bristled toothbrush and a fluoride toothpaste.
 - Flossing:
 - Recommend daily flossing to remove plaque and debris from between the teeth and around the fixed restoration. A floss threader may be needed for hard-to-reach areas.
 - Mouthwash:
 - Alcohol-based mouthwashes tend to dry out the mouth and lead to increased plaque and tartar buildup.

Dietary and Habit Recommendations

- Avoid abrasive foods: Limit hard, crunchy, or sticky foods that can damage the restoration or cause it to loosen.
- Avoid sugary foods: where new cavities can form or cause premature decay of the restorative margins.
- Stay hydrated: Drinking plenty of water will help keep your patient's mouth clean and prevent gum disease.
- Avoid bad habits: Refrain from using teeth to open packages or biting on hard objects

6) Storage

Stored in specialized boxes with foam or membranes for protection, often made of ABS plastic. For patients who lose a crown, store it in a sealed bag or a small container with a small amount of water to keep it safe and moist until the dentist's visit.

7) Expected Life / Service

They offer exceptional longevity, typically lasting 20 years or more, often extending to 30 years or even a lifetime with excellent care, thanks to their unmatched durability, resistance to chipping, and precise fit.

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

- Dandy asks that restorations that contain precious metals created by Dandy that need refabrication, be returned to us.
- Disposing of metal dental restorations involves either recycling them as precious metals (especially if gold alloy) through specialized refineries or scrap dealers for value, or general recycling if non-precious (like steel), but never in regular trash.
 - Precious Metal Refining: Many dental restorations contain valuable metals, making them a valuable asset for recycling.
 - Specialized Refiners: Some companies offer mail-in programs where you send in your scrap in prepaid, insured envelopes for assay and payment.
- How it Works: You send your restorations, they refine the metals, and pay you based on current market prices, often with insured shipping.
- For Non-Precious Metal Restorations
 - Dandy restorations that need refabrication, do not have to be returned to us.
 - Scrap Metal Dealers: various scrap metals, offering pickup or drop-off, though you'd need to confirm if they take small dental items.
 - General Recycling: Check with your local sanitation department for guidelines on disposing of bulk or metal items if it's not a dental office scenario.

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
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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 /
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Signatory Table

Action Name	User Name	Title	Signature Date
Approve	Kasha Lim	Supplier Quality Engineer	12-Jun-2026 01:53

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