

INSTRUCTIONS FOR USE (IFU)

Dandy / Zima International, Inc. | AUS · NZ · UK · EU/EN · EU/ES · EU/FR · EU/DE · EU/IT · EU/DA ·
EU/NL · EU/PL · EU/SV · EU/NB · EU/PT

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	Bridge - Polymer
GMDN / EMDN Code	37542
Product Code(s)	PMMASBRA, PMMASBRP
Device Type	Custom-made dental device (CMD) / Patient Matched Medical Device (PMMD)
Sterility	Not supplied sterile
Single-use / Reuse	Single-use
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	37542
Product Code(s)	PMMASBRA, PMMASBRP
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 (if applicable)
Single-use / Reusable	Single-use

1) Intended Purpose (Intended Use)

Dandy's temporary bridges are made to provisionally restore worn, carious, broken, and aesthetically displeasing dentition.

They:

- Replace one or more missing permanent teeth (bridges) by spanning the edentulous space and being supported by natural teeth or dental implants
- Restore the form, function, and esthetics of natural dentition.
- Provide occlusal stability and maintain proper interarch relationships.
- Provide a preview of the final restoration.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Dandy's temporary bridges (PMMA) are fabricated using digital technology, allowing for a precise fit and customization to the patient's specific needs. They are made of a highly durable and biocompatible material, ensuring long-term comfort and function. PMMA, which stands for polymethyl methacrylate, is not intended for short-term use.
- Material: Argen PMMA

[Temporary Crown and Bridge Material Safety Data Sheet](#)

3) Contraindications

Temporary crowns should be used with caution in patients with uncontrolled periodontal disease, severe bone resorption, active caries, or oral lesions.

4) Warnings / Precautions / Potential Risks

⚠ WARNING

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

***Warning – Irritation:**

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

⚠ CAUTION

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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 (for bridges). Care must be taken to prevent the dislodging of the restoration.

Mouthwash:

- Alcohol-based mouthwashes tend to dry out the mouth, leading 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, as they can form new cavities or cause premature decay of the restorative margins.
- Stay hydrated: Drinking plenty of water helps keep your patient's mouth clean and prevents gum disease.
- Avoid bad habits: Refrain from using teeth to open packages or biting on hard objects.

6) Storage

Requires a cool, dry place, protected from direct sunlight, extreme heat (above 77°F/25°C), moisture, dust, and contamination, as these conditions can degrade the material or compromise its integrity, affecting temporary use and ultimately impacting shelf life and performance.

7) Expected Life / Service

PMMA (polymethyl methacrylate) dental bridges generally last 3 to 5 years, but often require more frequent attention than other materials, depending heavily on oral hygiene, habits (avoiding hard/sticky foods), bridge design, and location (front vs. back teeth).

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

- Disposal of PMMA (Polymethyl Methacrylate) dental restorations involves recycling, often through specialized dental waste handlers who can chemically break it down into its monomer (MMA) or manage it as plastic. However, it should not be placed in the general trash due to environmental concerns.
- Fully cured PMMA might also be treated like general plastic waste if not mixed with metals or hazardous components.
- No Regular Trash: Do not dispose of PMMA dental waste in the regular garbage or medical waste streams.
- Hazardous Components: If mixed with solvents or other hazardous materials, it requires specific hazardous waste handling.

NEW ZEALAND (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

New Zealand— Patient Matched Medical Device (PMMD)

GMDN / EMDN	37542
Product Code(s)	PMMASBRA, PMMASBRP
Manufacturer	Zima International, Inc. Also DBA Dandy 1320 N. 300 W., Lehi, UT 84043 United States
New Zealand Sponsor	Name: DANDY Labs NZ Limited Address: Quigg Partners, Level 7, 36 Brandon Street, Wellington, NZ 6011
Intended User	Prescriber — Dental professional / dental practice
Device Type	Patient Matched Medical Device (PMMD)
Sterility	Not supplied sterile (if applicable)
Single-use / Reusable	Single-use

1) Intended Purpose (Intended Use)

Dandy's temporary bridges are made to provisionally restore worn, carious, broken, and aesthetically unpleasing dentition.

They:

- Replace one or more missing permanent teeth (bridges) by spanning the edentulous space and being supported by natural teeth or dental implants
- Restore the form, function, and esthetics of natural dentition.
- Provide occlusal stability and maintain proper interarch relationships.
- Provide a preview of the final restoration.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Dandy's temporary bridges (PMMA) are fabricated using digital technology, allowing for a precise fit and customization to the patient's specific needs. They are made of a highly durable and biocompatible material, ensuring long-term comfort and function. PMMA, which stands for polymethyl methacrylate, is not intended for short-term use.
- Material: Argen PMMA

[Temporary Crown and Bridge Material Safety Data Sheet](#)

3) Contraindications

Temporary crowns should be used with caution in patients with uncontrolled periodontal disease, severe bone resorption, active caries, or oral lesions.

4) Warnings / Precautions / Potential Risks

WARNING

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

***Warning – Irritation:**

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

CAUTION

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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 (for bridges). Care must be taken to prevent the dislodging of the restoration.

Mouthwash:

- Alcohol-based mouthwashes tend to dry out the mouth, leading 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, as they can form new cavities or cause premature decay of the restorative margins.
- Stay hydrated: Drinking plenty of water helps keep your patient's mouth clean and prevents gum disease.
- Avoid bad habits: Refrain from using teeth to open packages or biting on hard objects.

6) Storage

Requires a cool, dry place, protected from direct sunlight, extreme heat (above 77°F/25°C), moisture, dust, and contamination, as these conditions can degrade the material or compromise its integrity, affecting temporary use and ultimately impacting shelf life and performance.

7) Expected Life / Service

PMMA (polymethyl methacrylate) dental bridges generally last 3 to 5 years, but often require more frequent attention than other materials, depending heavily on oral hygiene, habits (avoiding hard/sticky foods), bridge design, and location (front vs. back teeth).

8) Incident / Complaint Reporting

Report suspected serious incidents associated with this device to:

- The Manufacturer and/or Dandy New Zealand entity using the contacts above, and
- Medsafe

In New Zealand, serious incidents and quality issues involving medical devices should be reported to Medsafe in accordance with New Zealand's medical device adverse event reporting requirements.

INFO

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

9) Disposal

- Disposal of PMMA (Polymethyl Methacrylate) dental restorations involves recycling, often through specialized dental waste handlers who can chemically break it down into its monomer (MMA) or manage it as plastic. However, it should not be placed in the general trash due to environmental concerns.
- Fully cured PMMA might also be treated like general plastic waste if not mixed with metals or hazardous components.
- No Regular Trash: Do not dispose of PMMA dental waste in the regular garbage or medical waste streams.
- Hazardous Components: If mixed with solvents or other hazardous materials, it requires specific hazardous waste handling.

EUROPEAN UNION (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

European Union — Custom-Made Device (CMD)

GMDN / EMDN	Q010206- Dental Prostheses
Product Code(s)	PMMASBRA, PMMASBRP
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 (if applicable)
Single-use / Reusable	Single-use

1) Intended Purpose (Intended Use)

Dandy's temporary bridges are made to provisionally restore worn, carious, broken, and aesthetically displeasing dentition.

They:

- Replace one or more missing permanent teeth (bridges) by spanning the edentulous space and being supported by natural teeth or dental implants
- Restore the form, function, and esthetics of natural dentition.
- Provide occlusal stability and maintain proper interarch relationships.
- Provide a preview of the final restoration.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Dandy's temporary bridges (PMMA) are fabricated using digital technology, allowing for a precise fit and customization to the patient's specific needs. They are made of a highly durable and biocompatible material, ensuring long-term comfort and function. PMMA, which stands for polymethyl methacrylate, is not intended for short-term use.
- Material: Argen PMMA

[Temporary Crown and Bridge Material Safety Data Sheet](#)

3) Contraindications

Temporary crowns should be used with caution in patients with uncontrolled periodontal disease, severe bone resorption, active caries, or oral lesions.

4) Warnings / Precautions / Potential Risks

⚠ **WARNING**

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

***Warning – Irritation:**

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

⚠ **CAUTION**

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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 (for bridges). Care must be taken to prevent the dislodging of the restoration.

Mouthwash:

- Alcohol-based mouthwashes tend to dry out the mouth, leading 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, as they can form new cavities or cause premature decay of the restorative margins.
- Stay hydrated: Drinking plenty of water helps keep your patient's mouth clean and prevents gum disease.
- Avoid bad habits: Refrain from using teeth to open packages or biting on hard objects.

6) Storage

Requires a cool, dry place, protected from direct sunlight, extreme heat (above 77°F/25°C), moisture, dust, and contamination, as these conditions can degrade the material or compromise its integrity, affecting temporary use and ultimately impacting shelf life and performance.

7) Expected Life / Service

PMMA (polymethyl methacrylate) dental bridges generally last 3 to 5 years, but often require more frequent attention than other materials, depending heavily on oral hygiene, habits (avoiding hard/sticky foods), bridge design, and location (front vs. back teeth).

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

- Disposal of PMMA (Polymethyl Methacrylate) dental restorations involves recycling, often through specialized dental waste handlers who can chemically break it down into its monomer (MMA) or manage it as plastic. However, it should not be placed in the general trash due to environmental concerns.
- Fully cured PMMA might also be treated like general plastic waste if not mixed with metals or hazardous components.
- No Regular Trash: Do not dispose of PMMA dental waste in the regular garbage or medical waste streams.
- Hazardous Components: If mixed with solvents or other hazardous materials, it requires specific hazardous waste handling.

UNIÓN EUROPEA (ESPAÑOL)

INSTRUCCIONES DE USO (IFU)

Unión Europea — Producto Sanitario a Medida (CMD)

GMDN / EMDN	Q010206- Prótesis dentales
Código(s) del producto	PMMASBRA, PMMASBRP

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	Prescriber — Dental professional / dental practice
Tipo de dispositivo	Dispositivo dental a medida (CMD)
Esterilidad	No se suministra estéril (si procede)
De un solo uso / Reutilizable	un solo uso

1) Finalidad prevista (uso previsto)

Los puentes provisionales de Dandy están diseñados para restaurar provisionalmente dentición desgastada, cariada, fracturada o estéticamente insatisfactoria.

Los puentes:

- Sustituyen uno o varios dientes permanentes ausentes (puentes) al salvar el espacio edéntulo y apoyarse en dientes naturales o implantes dentales.
- Restauran la forma, la función y la estética de la dentición natural.
- Proporcionan estabilidad oclusal y mantienen unas relaciones interarcales adecuadas.
- Proporcionan una vista previa de la restauración definitiva.

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 puentes temporales de Dandy (PMMA) están fabricados con tecnología digital, lo que permite un ajuste preciso y una personalización a las necesidades específicas del paciente. Están fabricados con un material altamente duradero y biocompatible, lo que garantiza confort y funcionalidad a largo plazo. El PMMA, siglas de polimetilmetacrilato, no está indicado para un uso prolongado.

- Material: Argen PMMA

[Ficha de datos de seguridad del material de coronas y puentes temporales](#)

3) Contraindicaciones

Las coronas temporales deben utilizarse con precaución en pacientes con enfermedad periodontal no controlada, resorción ósea grave, caries activas o lesiones orales.

4) Advertencias / Precauciones / Riesgos potenciales

⚠ **ADVERTENCIAS**

El uso de puentes temporales puede entrañar riesgos potenciales, como fallo, ajuste incorrecto, rotura y caries recurrentes.

***Advertencia – Irritación:**

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

⚠ **PRECAUCION**

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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 (en el caso de los puentes). Debe tenerse cuidado para evitar el desprendimiento de la restauración.

Enjuague bucal:

- Los enjuagues bucales a base de alcohol tienden a secar la boca, lo que provoca un aumento de la placa y la acumulación de 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 ayuda a mantener limpia la boca del paciente y a prevenir la enfermedad periodontal.

- Evite los malos hábitos: Absténgase de usar sus dientes para abrir paquetes o morder objetos duros.

6) Almacenamiento

Debe conservarse en un lugar fresco y seco, protegido de la luz solar directa, el calor extremo (superior a 25 °C/77 °F), la humedad, el polvo y la contaminación, ya que estas condiciones pueden degradar el material o comprometer su integridad, afectando a su uso provisional y, en última instancia, a su vida útil y rendimiento.

7) Vida esperada / Servicio

Los puentes dentales de PMMA (polimetilmetacrilato) suelen durar entre 3 y 5 años, aunque a menudo requieren más atención que otros materiales, dependiendo en gran medida de la higiene bucal, los hábitos del paciente (evitar alimentos duros o pegajosos), el diseño del puente y su localización (dientes anteriores frente a posteriores).

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

- La eliminación de restauraciones dentales de PMMA (polimetilmetacrilato) implica su reciclaje, a menudo a través de gestores especializados en residuos dentales que pueden descomponerlo químicamente en su monómero (MMA) o gestionarlo como plástico. Sin embargo, no debe desecharse junto a la basura general, debido a problemas medioambientales.

- El PMMA totalmente curado también puede tratarse como residuos plásticos generales si no se mezcla con metales o componentes peligrosos.
- No desechar junto con los residuos domésticos. No deseche los residuos dentales de PMMA en la basura convencional ni junto con los residuos sanitarios.
- Componentes peligrosos: Si se mezcla con disolventes u otros materiales peligrosos, requiere una manipulación específica de residuos peligrosos.

UNION EUROPÉENNE (FRANÇAIS)

INSTRUCTIONS D'UTILISATION (IFU)

Union Européenne — Dispositif sur Mesure (CMD)

GMDN / EMDN	Q010206- Prothèses dentaires
Code(s) produit	PMMASBRA, PMMASBRP
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	Usage unique

1) Usage prévu (utilisation prévue)

Les bridges provisoires Dandy sont conçus pour restaurer temporairement une dentition usée, cariée, fracturée ou inesthétique.

Ils :

- Remplacent une ou plusieurs dents définitives manquantes (ponts) en comblant l'espace édenté et en s'appuyant sur des dents naturelles ou des implants dentaires .
- Rétablissent la forme, la fonction et l'esthétique de la dentition naturelle.
- Assurent la stabilité occlusale et préservent les relations interarcades correctes.
- Fournir un aperçu de la restauration finale.

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 bridges provisoires Dandy (en PMMA) sont fabriqués à l'aide d'une technologie numérique, ce qui garantit un ajustement précis et une adaptation aux besoins spécifiques du patient. Ils sont fabriqués à partir d'un matériau hautement durable et biocompatible, assurant confort et fonctionnalité à long terme. Le PMMA, qui signifie polyméthacrylate de méthyle, n'est pas destiné à une utilisation à court terme.
- Matériel : Argen PMMA

Fiche de données de sécurité des matériaux utilisés pour les couronnes et les bridges provisoires

3) Contre-indications

Les couronnes temporaires doivent être utilisées avec prudence chez les patients présentant une maladie parodontale non contrôlée, une résorption osseuse sévère, des caries actives ou des lésions buccodentaires.

4) Avertissements / Précautions / Risques potentiels

⚠️ AVERTISSEMENTS

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

***Avertissement – Irritation :**

Une irritation localisée des tissus buccaux environnants peut se produire chez des individus spécifiques en raison de la variabilité individuelle de la réponse tissulaire. Les patients doivent faire l'objet d'une surveillance après la pose, et le praticien traitant doit évaluer tout signe d'irritation, d'inflammation ou de gêne.

⚠️ PRECAUTIONS

na

5) Nettoyage et entretien

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

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 enfilé-fil dentaire peut s'avérer nécessaire pour les zones difficiles d'accès (comme les bridges). Il faut veiller à ce que la restauration ne se déloge pas.

Bain de bouche :

- Les bains de bouche à base d'alcool ont tendance à sécher la bouche, ce qui entraîne 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, car ils peuvent former de nouvelles cavités ou provoquer une dégradation prématurée des marges de restauration.
- Rester hydraté : Boire beaucoup d'eau aide à garder la bouche de votre patient propre et prévient 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

Nécessite un endroit frais et sec, à l'abri de la lumière directe du soleil, de la chaleur excessive (supérieure à 25°C), de l'humidité, de la poussière et de toute contamination, car ces conditions peuvent altérer le matériau ou compromettre son intégrité, ce qui affecterait son utilisation temporaire et, à terme, sa durée de conservation et ses performances.

7) Durée de vie / Service attendu

Les bridges dentaires en PMMA (polyméthacrylate de méthyle) ont généralement une durée de vie de 3 à 5 ans, mais nécessitent souvent un entretien plus fréquent que ceux fabriqués dans d'autres matériaux. Cela dépend fortement de l'hygiène bucco-dentaire, des habitudes alimentaires (il faut éviter les aliments durs ou collants), de la conception du bridge et de son emplacement (dents de devant ou de derrière).

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

- L'élimination des restaurations dentaires en PMMA (polyméthacrylate de méthyle) passe par le recyclage, souvent par l'intermédiaire d'entreprises spécialisées dans le traitement des déchets dentaires, qui peuvent le décomposer chimiquement en son monomère (MMA) ou le traiter

comme du plastique. Toutefois, pour des raisons environnementales, il ne doit pas être jeté avec les ordures ménagères.

- Le PMMA entièrement polymérisé peut également être traité comme un déchet plastique ordinaire s'il n'est pas mélangé à des métaux ou à des composants dangereux.
- Pas de déchets ménagers : Ne pas jeter les déchets dentaires en PMMA avec les ordures ménagères ni avec les déchets médicaux.
- Composants dangereux : En cas de mélange avec des solvants ou d'autres matières dangereuses, il nécessite un traitement spécifique des déchets dangereux.

EUROPÄISCHE UNION (DEUTSCH)

GEBRAUCHSANWEISUNG (IFU)

EU-SONDERANFERTIGUNG (CMD – Sonderanfertigung)

GMDN / EMDN	37542
Produktcode(s)	PMMASBRA, PMMASBRP
Hersteller	Zima International, Inc., auch DBA 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, Frankreich
Vorgesehener Anwender	Verschreibende(r) Zahnarzt/Zahnarztpraxis
Gerätetyp	Zahntechnische Sonderanfertigung (CMD)
Sterilität	Wird nicht steril geliefert (falls zutreffend)
Einmalprodukt/wiederverwendbar:	Einmalgebrauch

1) Zweckbestimmung (Verwendungszweck)

Dandy provisorische Brücken sind für die temporäre Restauration von abradertem, kariösem, frakturiertem und ästhetisch unvorteilhaftem Gebiss konzipiert.

Sie:

- Ersetzen Sie einen oder mehrere fehlende bleibende Zähne (Brücken), indem Sie die zahnlose Lücke überspannen, wobei die Abstützung durch natürliche Zähne oder Zahnimplantate erfolgt.
- Zur Wiederherstellung von Form, Funktion und Ästhetik des natürlichen Gebisses.
- Gewährleisten okklusale Stabilität und erhalten die korrekte Kieferrelation.
- Sie geben eine Vorschau auf die endgültige Restauration.

2) Produktbeschreibung / Hauptspezifikationen

- Maßgefertigte, patientenspezifische Sonderanfertigung, hergestellt nach zahnärztlicher Verordnung und digitalen Eingabedaten.
- Konfiguration: Dandy provisorische Brücken (PMMA) werden mittels digitaler Technologie gefertigt, was eine präzise Passform sowie eine exakte Abstimmung auf die spezifischen Bedürfnisse des Patienten ermöglicht. Sie bestehen aus einem hochgradig langlebigen und biokompatiblen Material, was langfristigen Komfort und uneingeschränkte Funktion

gewährleistet. PMMA, was für Polymethylmethacrylat steht, ist nicht für den kurzzeitigen Einsatz gedacht.

- Material: Argen PMMA

[Sicherheitsdatenblatt für provisorische Kronen und Brücken](#)

3) Kontraindikationen

Provisorische Kronen sollten bei Patienten mit unkontrollierter Parodontalerkrankung, schwerer Knochenresorption, aktiver Karies oder Läsionen der Mundschleimhaut nur mit Vorsicht eingesetzt werden

4) Warnhinweise / Vorsichtsmaßnahmen / Potenzielle Risiken

⚠ **WARNHINWEISE**

Die Verwendung von provisorischen Brücken birgt potenzielle Risiken, einschließlich Versagen, Passungenauigkeit, Bruch und Sekundärkaries.

*Warnhinweis – Reizung:

- Aufgrund der individuellen Variabilität der Gewebereaktion kann es bei spezifischen 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 bewerten.

⚠ **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 festsitzenden Zahnersatzes zu entfernen. Für schwer zugängliche Bereiche (bei Brücken) kann eine Einfädelhilfe für Zahnseide erforderlich sein. Es muss sorgfältig darauf geachtet werden, ein Ablösen der Restauration zu verhindern.
- 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.
- Verzicht auf zuckerhaltige Lebensmittel, da diese die Entstehung von neuer Karies begünstigen und zu einem vorzeitigen Abbau der Kronen- und Brückenränder führen können.
- Hydriert bleiben: Das Trinken von reichlich Wasser trägt dazu bei, die Mundhöhle des Patienten sauber zu halten und Parodontalerkrankungen vorzubeugen.

- Vermeidung schlechter Gewohnheiten: Verzichten Sie darauf, die Zähne zum Öffnen von Verpackungen oder zum Beißen auf harte Gegenstände zu verwenden.

6) Lagerung

Erfordert eine kühle, trockene Lagerung, geschützt vor direkter Sonneneinstrahlung, extremer Hitze (über 25 °C / 77 °F), Feuchtigkeit, Staub und Kontamination, da diese Bedingungen das Material zersetzen oder seine Integrität beeinträchtigen können, was den temporären Einsatz stört und sich letztlich negativ auf die Haltbarkeit sowie die Leistungsfähigkeit auswirkt

7) Erwartete Lebensdauer / Nutzungsdauer

PMMA-Zahnersatz (Polymethylmethacrylat-Brücken) hält in der Regel 3 bis 5 Jahre, erfordert jedoch häufiger eine zahnärztliche Kontrolle als andere Materialien. Dies hängt stark von der Mundhygiene, den Gewohnheiten (Vermeiden harter oder klebriger Lebensmittel), dem Brückendesign und der Lokalisation (Front- vs. Backenzähne) ab

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 Vertreter" – am Ende des Dokuments..

9) Entsorgung

Die Entsorgung von PMMA-Zahnersatz (Polymethylmethacrylat-Restaurationen) erfolgt über das Recycling, häufig durch spezialisierte Entsorgungsunternehmen für spezifische zahnärztliche Abfälle, die das Material chemisch in sein Monomer (MMA) zerlegen oder es als Kunststoffabfall verwerten können. Aus Umweltschutzgründen sollten diese jedoch nicht über den normalen Hausmüll entsorgt werden.

- Vollständig ausgehärtetes PMMA kann auch wie normaler Kunststoffabfall behandelt werden, sofern es nicht mit Metallen oder gefährlichen Komponenten vermischt ist.

- Kein normaler Hausmüll: Zahntechnische PMMA-Abfälle dürfen nicht über den normalen Hausmüll oder den regulären medizinischen Abfallstrom entsorgt werden.
- Gefährliche Bestandteile: Bei einer Vermischung mit Lösungsmitteln oder anderen Gefahrstoffen ist eine spezifische Gefahrgutabfall-Handhabung erforderlich.

UNIONE EUROPEA (ITALIANO)

ISTRUZIONI PER L'USO (IFU)

DISPOSITIVO PERSONALIZZATO UE (CMD = Dispositivo personalizzato)

GMDN / EMDN	37542
Codici prodotto	PMMASBRA, PMMASBRP

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

Utente previsto	Prescrittore — Professionista dentale / Studio dentistico
Tipo di dispositivo	Dispositivo dentale su misura (CMD)
Sterilità	Not supplied sterile (if applicable)
Monouso / Riutilizzabile	Monouso

1) Scopo previsto (uso previsto)

I ponti temporanei di Dandy sono realizzati per ripristinare provvisoriamente denti usurati, cariati, fratturati ed esteticamente non soddisfacenti.

Questi dispositivi:

- Sostituiscono uno o più denti permanenti mancanti (ponti) estendendo lo spazio edentulo e sono supportati da denti naturali o impianti dentali
- Ripristinano la forma, la funzione e l'estetica della dentatura naturale.
- Forniscono stabilità occlusale e mantengono le corrette relazioni tra le arcate.
- Forniscono un'anteprima del restauro finale.

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 ponti temporanei di Dandy (PMMA) sono realizzati utilizzando la tecnologia digitale, consentendo una precisa vestibilità e personalizzazione in base alle esigenze specifiche del paziente. Sono realizzati in materiale altamente resistente e biocompatibile, garantendo comfort e funzionalità a lungo termine. Il PMMA, acronimo di polimetilmetacrilato, non è destinato all'uso a breve termine.
- Materiale: Argen PMMA

[Scheda di sicurezza del materiale di corone e ponti temporanei](#)

3) Controindicazioni

Le corone temporanee devono essere utilizzate con cautela in pazienti con malattia parodontale non controllata, grave riassorbimento osseo, carie attive o lesioni orali.

4) Avvertenze / Precauzioni / Rischi potenziali

⚠ **AVVERTENZE**

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

*Avvertenza – Irritazione:

- In individui specifici 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 disagio..

⚠ **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 (per ponti). Prestare attenzione per evitare lo spostamento del restauro.
- 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 cibi zuccherati, in quanto possono formare nuove cavità o causare un decadimento prematuro dei margini di restauro.
- Rimanere idratati: bere molta acqua aiuta a mantenere pulita la bocca del paziente e previene le malattie gengivali.
- Evitare cattive abitudini: evitare di usare i denti per aprire pacchetti o mordere oggetti duri.

6) Conservazione

Richiede un luogo fresco e asciutto, protetto dalla luce solare diretta, dal calore estremo (oltre 25 °C/77 °F), dall'umidità, dalla polvere e dalla contaminazione, in quanto queste condizioni possono degradare il materiale o comprometterne l'integrità, compromettendo l'uso temporaneo e, in ultima analisi, la durata di conservazione e le prestazioni.

7) Durata prevista / Assistenza

I ponti dentali in PMMA (polimetilmetacrilato) durano generalmente da 3 a 5 anni, ma spesso richiedono un'attenzione più frequente rispetto ad altri materiali, poiché dipendono notevolmente dall'igiene orale, dalle abitudini (evitare cibi duri/appiccicosi), dal design del ponte e dalla posizione (denti anteriori e posteriori).

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)

INFO

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

9) Smaltimento

Lo smaltimento dei restauri dentali in PMMA (polimetilmetacrilato) comprende il riciclaggio, spesso attraverso addetti specializzati in rifiuti dentali che li possono scomporre chimicamente nel monomero (MMA) o gestirli come materiale plastico. Tuttavia, non dovrebbero essere buttati tra i rifiuti indifferenziati a causa dei problemi ambientali.

- Se non miscelato con metalli o componenti pericolosi, il PMMA completamente polimerizzato potrebbe anche essere trattato come rifiuto plastico generico.
- Non gettare tra i rifiuti regolari: non smaltire i rifiuti dentali in PMMA tra i normali rifiuti o nei flussi di rifiuti medici.
- Componenti pericolosi: se miscelato con solventi o altri materiali pericolosi, richiede una gestione specifica dei rifiuti pericolosi.

UNITED KINGDOM (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

United Kingdom — Custom-Made Device (CMD)

GMDN / EMDN	37542
Product Code(s)	PMMASBRA, PMMASBRP
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	Single-use

1) Intended Purpose (Intended Use)

Dandy's temporary bridges are made to provisionally restore worn, carious, broken, and aesthetically unpleasing dentition.

They:

- Replace one or more missing permanent teeth (bridges) by spanning the edentulous space and being supported by natural teeth or dental implants
- Restore the form, function, and esthetics of natural dentition.
- Provide occlusal stability and maintain proper interarch relationships.
- Provide a preview of the final restoration.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Dandy's temporary bridges (PMMA) are fabricated using digital technology, allowing for a precise fit and customization to the patient's specific needs. They are made of a highly durable and biocompatible material, ensuring long-term comfort and function. PMMA, which stands for polymethyl methacrylate, is not intended for short-term use.
- Material: Argen PMMA

Temporary Crown and Bridge Material Safety Data Sheet

3) Contraindications

Temporary crowns should be used with caution in patients with uncontrolled periodontal disease, severe bone resorption, active caries, or oral lesions.

4) Warnings / Precautions / Potential Risks

⚠ WARNING

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

***Warning – Irritation:**

Localized irritation of surrounding oral tissues may occur in specific individuals due to individual variability in tissue response. Patients should be monitored after placement, and the treating clinician should assess 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 (for bridges). Care must be taken to prevent the dislodging of the restoration.

Mouthwash:

- Alcohol-based mouthwashes tend to dry out the mouth, leading 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, as they can form new cavities or cause premature decay of the restorative margins.
- Stay hydrated: Drinking plenty of water helps keep your patient's mouth clean and prevents gum disease.
- Avoid bad habits: Refrain from using teeth to open packages or biting on hard objects.

6) Storage

Requires a cool, dry place, protected from direct sunlight, extreme heat (above 77°F/25°C), moisture, dust, and contamination, as these conditions can degrade the material or compromise its integrity, affecting temporary use and ultimately impacting shelf life and performance.

7) Expected Life / Service

PMMA (polymethyl methacrylate) dental bridges generally last 3 to 5 years, but often require more frequent attention than other materials, depending heavily on oral hygiene, habits (avoiding hard/sticky foods), bridge design, and location (front vs. back teeth).

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

- Disposal of PMMA (Polymethyl Methacrylate) dental restorations involves recycling, often through specialized dental waste handlers who can chemically break it down into its monomer (MMA) or manage it as plastic. However, it should not be placed in the general trash due to environmental concerns.
- Fully cured PMMA might also be treated like general plastic waste if not mixed with metals or hazardous components.
- No Regular Trash: Do not dispose of PMMA dental waste in the regular garbage or medical waste streams.
- Hazardous Components: If mixed with solvents or other hazardous materials, it requires specific hazardous waste handling.

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
New Zealand (NZ)	DANDY Labs NZ Limited	Quigg Partners, Level 7, 36 Brandon Street, Wellington, NZ 6011	NZBN: 942905375844 6	Medsafe

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 /
Fabbrikante / Fabricant /
Fabricante

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Signatory Table

Action Name	User Name	Title	Signature Date
Approve	Nicole Sheldon	Senior Quality Engineer	07-Aug-2026 17:12

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