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	Implant Abutment
GMDN / EMDN Code	63349
Product Code(s)	TICLOCDES, TICLOCMED, TICLOCMEG, TICLOCNOB, TICLOCSTR, TICLOCZIM
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	63349
Product Code(s)	TICLOCDES, TICLOCMED, TICLOCMEG, TICLOCNOB, TICLOCSTR, TICLOCZIM

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	Single use

1) Intended Purpose (Intended Use)

These dental abutments are connected directly to an endosseous implant for use as an aid in prosthetic rehabilitation. The abutment is designed with a scalloped cuff that profiles the natural contours of soft tissue and is custom-made to meet your patient's specific needs. Made from titanium, titanium alloy, or Zirconia. The abutment gets restored with a crown, bridge, or is used to anchor a restorative device.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Dental abutments are designed to be used in the Maxilla or mandible to support a prosthesis on endosseous implants, thereby restoring chewing function for the patient.
- Material: Titanium/Zirconia

Zirconia

3) Contraindications

Do not use in patients:

- Those who are medically unfit for dental implant procedures.
- Those who are allergic or have hypersensitivity to pure titanium or titanium alloy.

- Those where adequate numbers of implants could not be placed to achieve full functional support for a prosthesis.

4) Warnings / Precautions / Potential Risks

THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING

⚠ WARNING

- For safe and effective use of dental implants, it is strongly suggested that specialised training be undertaken, including hands-on training to learn proper technique, biomechanical requirements, and radiographic evaluations.
- Responsibility for proper patient selection, adequate training, experience in implant placement, and providing appropriate information for informed consent rests with the practitioner. Improper technique can result in implant failure, damage to nerves/vessels, and/or loss of supporting bone.

⚠ CAUTION

- New and experienced Implant users should do training before using a new system or attempting a new treatment method.
- Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue. (e.g., poor oral hygiene, uncontrolled diabetes, are on steroid therapy, smokers, infection in the nearby bone, and patients who had oro-facial radiotherapy.)
- Remove the temporary restoration if applicable.
- Verify and re-tighten the screw if applicable. Seal the screw access hole with silicone and cement the final crown using conventional procedures.
- Make sure that all excess cement is removed from the margin.
- Overtightening of the abutment may lead to screw fracture)
- Cement the final crown or framework using conventional procedures after sealing the access hole, ensuring there's no excess cement on the margin.
- For screw retained restorations
- The final restoration (crown and abutment) is attached to the implant
- Verify the seating
- Tighten the screw to the required torque. (Do not exceed the recommended tightening torque for the abutment screw.

5) Cleaning and Care

These abutments are not supplied sterile and are intended for single use

6) Storage

The product must be stored in a dry, well-ventilated area at room temperature and protected from direct sunlight.

Incorrect storage may influence device characteristics

7) Expected Life / Service

A dental abutment typically lasts 10 to 20+ years, often aligning with the crown's lifespan, but can last longer with excellent care; it usually outlasts the crown (10-15 yrs) but is less durable than the implant

post. Longevity depends on material, chewing forces (molars wear faster), and habits like grinding (bruxism). Still, good hygiene and regular checkups are key to maximizing its life, with some studies showing great success with all-ceramic options.

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

Must be disposed of as biological or medical waste if they have been used in a patient's mouth

Unused abutments (Titanium or Zirconia) may be disposed of as general waste

Guidelines:

Used Abutments:

Any dental restoration or component that has been in the patient's mouth is considered biological waste and must be handled and disposed of according to strict medical waste management regulations.

Unused Abutments:

If the custom abutment is unused and has not been sterilized or come into contact with bodily fluids, it may not fall under the same strict biohazard rules.

Material:

Titanium/Zirconia: The materials themselves (titanium alloy, zirconia) are not inherently hazardous materials in their solid form, but their classification as waste is determined by their potential biohazard contamination during use or the preparation process.

Recycling:

While some materials are recyclable in general construction/demolition waste streams, dental practices must use certified medical waste streams to avoid regulatory non-compliance.

Follow Local Regulations: Disposal rules are governed by federal, state, and local health and environmental regulations. Ensure your practice is compliant with the specific requirements for your location.

EUROPEAN UNION (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

European Union — Custom-Made Device (CMD)

GMDN / EMDN	P01020180: Dental Implants - Accessories
Product Code(s)	TICLOCDES, TICLOCMED, TICLOCMEG, TICLOCNOB, TICLOCSTR, TICLOCZIM

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	Single use

1) Intended Purpose (Intended Use)

These dental abutments are connected directly to an endosseous implant for use as an aid in prosthetic rehabilitation. The abutment is designed with a scalloped cuff that profiles the natural contours of soft tissue and is custom-made to meet your patient's specific needs. Made from titanium, titanium alloy, or Zirconia. The abutment gets restored with a crown, bridge, or is used to anchor a restorative device.

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- For safe and effective use of dental implants, it is strongly suggested that specialised training be undertaken, including hands-on training to learn proper technique, biomechanical requirements, and radiographic evaluations.
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⚠ CAUTION

- New and experienced Implant users should do training before using a new system or attempting a new treatment method.
- Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue. (e.g., poor oral hygiene, uncontrolled diabetes, are on steroid therapy, smokers, infection in the nearby bone, and patients who had oro -facial radiotherapy.)
- Remove the temporary restoration if applicable.
- Verify and re-tighten the screw if applicable. Seal the screw access hole with silicone and cement the final "closed" crown using conventional procedures.
- Make sure that all excess cement is removed from the margin.
- Overtightening of the abutment may lead to screw fracture)
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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**
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UNIÓN EUROPEA (ESPAÑOL)

INSTRUCCIONES DE USO (IFU)

Unión Europea — Producto Sanitario a Medida (CMD)

GMDN / EMDN	P01020180: Implantes dentales - Accesorios
Código(s) del producto	TICLOCDES, TICLOCMED, TICLOCMEG, TICLOCNOB, TICLOCSTR, TICLOCZIM

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)

Estos pilares dentales están conectados directamente a un implante endoóseo para su uso como ayuda en la rehabilitación protésica. El pilar está diseñado con un manguito festoneado que reproduce los contornos naturales de los tejidos blandos y se fabrica a medida para satisfacer las necesidades específicas de su paciente. Fabricado en titanio, aleación de titanio o zirconia. El pilar se restaura con una corona o un puente, o bien se utiliza para anclar una restauración protésica.

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 pilares dentales están diseñados para su uso en el maxilar o la mandíbula para soportar una prótesis sobre implantes endoóseos, restaurando así la función masticatoria del paciente.
- Material: Titanio/circonio

Circonio

3) Contraindicaciones

No utilizar en los siguientes tipos de pacientes:

- Pacientes que no sean médicamente aptos para procedimientos de implantes dentales.

- Pacientes con alergia o hipersensibilidad al titanio puro o a las aleaciones de titanio.
- Pacientes en los que no pueda colocarse un número suficiente de implantes para proporcionar un soporte funcional completo a la prótesis.

4) Advertencias / Precauciones / Riesgos potenciales

ESTAS INSTRUCCIONES NO PRETENDEN SUSTITUIR A UNA FORMACIÓN ADECUADA

⚠ WARNING

- Para un uso seguro y eficaz de los implantes dentales, se recomienda encarecidamente una formación especializada, incluida formación práctica para aprender la técnica adecuada, los requisitos biomecánicos y la evaluación radiográfica.
- La responsabilidad de la correcta selección del paciente, la formación adecuada, la experiencia en la colocación de implantes y el suministro de información adecuada para obtener el consentimiento informado recae en el profesional. Una técnica incorrecta puede provocar el fracaso del implante, lesiones nerviosas o vasculares y/o pérdida del hueso de soporte.

⚠ CAUTION

- Tanto los usuarios nuevos como los experimentados de implantes deben recibir formación antes de utilizar un sistema nuevo o de intentar un nuevo método de tratamiento.
- Tenga especial cuidado al tratar a pacientes con factores locales o sistémicos que puedan afectar a la cicatrización del hueso y de los tejidos blandos (p. ej., higiene bucal deficiente, diabetes no controlada, tratamiento con esteroides, tabaquismo, infección en el hueso adyacente y pacientes que hayan recibido radioterapia orofacial).
- Retire la restauración provisional si procede.
- Verifique y vuelva a apretar el tornillo si procede. Selle el acceso al tornillo con silicona y cemente la corona definitiva “cerrada” utilizando procedimientos convencionales.
- Asegúrese de eliminar todo el exceso de cemento del margen.
- El apriete excesivo del pilar puede provocar la fractura del tornillo.
- Cemente la corona definitiva o la estructura mediante procedimientos convencionales tras sellar el acceso al tornillo, asegurándose de que no quede exceso de cemento en el margen.
- Para restauraciones atornilladas .
- La restauración definitiva (corona y pilar) se fija al implante.
- Compruebe el asentamiento.
- Apriete el tornillo al par de apriete necesario. (No exceda el par de apriete recomendado para el tornillo del pilar).

5) Limpieza y cuidado

Estos pilares no se suministran estériles y están diseñados para un solo uso.

6) Almacenamiento

El producto debe almacenarse en un lugar seco y bien ventilado a temperatura ambiente y protegido de la luz solar directa.

Un almacenamiento inadecuado puede afectar a las características del dispositivo.

7) Vida esperada / Servicio

Un pilar dental suele durar entre 10 y más de 20 años, a menudo en consonancia con la vida útil de la corona, aunque puede durar más con unos cuidados excelentes; por lo general dura más que la corona (10-15 años), pero es menos duradero que el implante. La longevidad depende del material, de las fuerzas masticatorias (los molares se desgastan más rápido) y de hábitos como el rechinamiento dental (bruxismo). Aun así, una buena higiene y revisiones periódicas son claves para maximizar su duración, y algunos estudios muestran un gran éxito con opciones totalmente cerámicas.

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

Deben eliminarse como residuo biológico o sanitario si se ha utilizado en la boca de un paciente.

Los pilares no utilizados (de titanio o zirconia) pueden eliminarse como residuos generales.

Directrices:

Pilares usados:

Cualquier restauración dental o componente que haya estado en la boca del paciente se considera un residuo biológico y debe manipularse y eliminarse de acuerdo con las estrictas normas de gestión de residuos médicos.

Pilares no utilizados:

Si el pilar personalizado no se utiliza y no se ha esterilizado ni entra en contacto con líquidos corporales, es posible que no esté sujeto a las mismas estrictas normas sobre riesgos biológicos.

Material:

Titanio/circonio: Los materiales en sí (aleación de titanio y zirconia) no son intrínsecamente peligrosos en estado sólido, pero su clasificación como residuo viene determinada por la posible contaminación biológica durante el uso o el proceso de preparación.

Reciclaje:

Aunque algunos materiales son reciclables dentro de los flujos generales de residuos de construcción y demolición, las clínicas dentales deben utilizar canales certificados para residuos sanitarios a fin de evitar incumplimientos normativos.

Siga la normativa local: Las normas de eliminación se rigen por la normativa estatal, autonómica y local en materia de salud y medio ambiente. Asegúrese de que su clínica cumple los requisitos específicos aplicables en su ubicación.

UNION EUROPÉENNE (FRANÇAIS)

INSTRUCTIONS D'UTILISATION (IFU)

Union Européenne — Dispositif sur Mesure (CMD)

GMDN / EMDN	P01020180 : Implants dentaires - Accessoires
Code(s) produit	TICLOCDES, TICLOCMED, TICLOCMEG, TICLOCNOB, TICLOCSTR, TICLOCZIM

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)

Ces pivots dentaires sont fixés directement sur un implant endo-osseux afin de faciliter la restauration prothétique. Le pivot est conçu avec un rebord festonné qui épouse les contours naturels des tissus mous et est fabriqué sur mesure pour répondre aux besoins spécifiques de votre patient. Fabriqué en titane, alliage de titane ou zircone. Le pivot est restauré à l'aide d'une couronne ou d'un bridge, ou sert à ancrer un appareil de restauration.

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 pivots dentaires sont conçus pour être utilisés dans le maxillaire ou la mandibule afin de soutenir une prothèse sur des implants endo-osseux, permettant ainsi au patient de retrouver sa fonction masticatoire.
- Matériel : Titane/zircone

Zircone

3) Contre-indications

Ne pas utiliser chez les patients :

- qui ne sont pas aptes, d'un point de vue médical, à subir une intervention d'implantation dentaire.
- qui présentent une allergie ou une hypersensibilité au titane pur ou aux alliages de titane.
- chez lesquels il n'a pas été possible de poser un nombre suffisant d'implants pour assurer un soutien fonctionnel complet de la prothèse.

4) Avertissements / Précautions / Risques potentiels

CES INSTRUCTIONS NE REMPLACENT PAS UNE FORMATION ADÉQUATE

⚠ AVERTISSEMENTS

Pour une utilisation sûre et efficace des implants dentaires, il est fortement recommandé de suivre une formation spécialisée, y compris une formation pratique pour apprendre les techniques appropriées, les exigences biomécaniques et les évaluations radiographiques.

La responsabilité de la sélection correcte des patients, de la formation adéquate, de l'expérience de la pose d'implants et de la fourniture d'informations appropriées pour le consentement éclairé incombe au praticien. Une technique incorrecte peut entraîner une défaillance de l'implant, des dommages aux nerfs/vaisseaux et/ou une perte de l'os de soutien.

⚠ PRECAUTIONS

- Les utilisateurs d'implants nouveaux et expérimentés doivent suivre une formation avant d'utiliser un nouveau système ou d'essayer une nouvelle méthode de traitement.
- Il convient de faire preuve d'une vigilance particulière lors du traitement de patients présentant des facteurs locaux ou systémiques susceptibles d'affecter la cicatrisation des os et des tissus mous (par exemple, une mauvaise hygiène bucco-dentaire, un diabète non contrôlé, un traitement aux stéroïdes, le tabagisme, une infection osseuse voisine ou des antécédents de radiothérapie au niveau de la région bucco-faciale).
- Retirer la restauration provisoire le cas échéant.
- Vérifier et resserrer la vis, le cas échéant. Sceller le trou d'accès de la vis avec du silicone et sceller la couronne finale « fermée » en utilisant les procédures conventionnelles.
- S'assurer que tout l'excès de ciment est éliminé du bord.
- Un serrage excessif du pivot peut entraîner une rupture de la vis .
- Cimenter la couronne ou l'ossature finale à l'aide de procédures conventionnelles après avoir scellé le trou d'accès, en veillant à ce qu'il n'y ait pas d'excès de ciment sur la marge.
- Pour les restaurations vissées .
- La restauration finale (couronne et pilier) est fixée à l'implant .
- Vérifier la mise en place .
- Serrer la vis au couple requis. (Ne pas dépasser le couple de serrage recommandé pour la vis du pivot.

5) Nettoyage et entretien

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

Ces pivots ne sont pas fournis stériles et sont à usage unique

6) Stockage

Le produit doit être stocké dans un endroit sec, bien ventilé, à température ambiante et protégé de la lumière directe du soleil.

Un stockage incorrect peut influencer les caractéristiques de l'appareil .

7) Durée de vie / Service attendu

Un pivot dentaire a généralement une durée de vie de 10 à plus de 20 ans, ce qui correspond souvent à celle de la couronne, mais il peut durer plus longtemps s'il est bien entretenu ; il dure généralement plus longtemps que la couronne (10 à 15 ans), mais il est moins résistant que le pilier de l'implant. La durée de vie dépend du matériau, de la force de mastication (les molaires s'usent plus rapidement) et de certaines habitudes comme le grincement des dents (bruxisme). Néanmoins, une bonne hygiène et des contrôles réguliers sont essentiels pour maximiser sa durée de vie, certaines études montrant un grand succès avec les options tout céramique.

8) Signalement des incidents / Réclamations

Signaler tout incident grave suspecté lié à cet appareil :

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

Competent Authorities:

- France: Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
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- 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

À éliminer comme déchets biologiques ou médicaux après utilisation dans la bouche d'un patient

Les pivots non utilisés (titane ou zircone) peuvent être éliminés comme déchets généraux

Lignes directrices :

Pivots utilisés :

- Toute restauration dentaire ou tout composant qui a été dans la bouche du patient est considéré comme un déchet biologique et doit être manipulé et éliminé conformément aux réglementations strictes en matière de gestion des déchets médicaux.

Pivots non utilisés :

- Si le pivot personnalisé n'est pas utilisé et n'a pas été stérilisé ou n'est pas entré en contact avec des liquides corporels, il peut ne pas être soumis aux mêmes règles strictes relatives aux risques biologiques.

Matériel :

- Titane/zircone : Les matériaux eux-mêmes (alliage de titane, zircone) ne sont pas intrinsèquement dangereux sous leur forme solide, mais leur classification en tant que déchets est déterminée par leur contamination biologique potentielle pendant l'utilisation ou le processus de préparation.

Recyclage :

- Bien que certains matériaux puissent être recyclés dans les flux de déchets de construction et de démolition courants, les cabinets dentaires doivent recourir à des filières de gestion des déchets médicaux certifiées afin d'éviter toute infraction à la réglementation.
- Respecter les réglementations locales : Les règles d'élimination sont régies par les réglementations sanitaires et environnementales fédérales, nationales et locales. Vérifier que votre cabinet respecte les exigences spécifiques à votre localisation.

EUROPÄISCHE UNION (DEUTSCH)

GEBRAUCHSANWEISUNG (IFU)

Europäische Union — Maßgefertigtes Medizinprodukt (CMD)

GMDN / EMDN	P01020180: Zahnimplantate − Zubehör
Produktcode(s)	TICLOCDES, TICLOCMED, TICLOCMEG, TICLOCNOB, TICLOCSTR, TICLOCZIM

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, Frankreich

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

1) Zweckbestimmung (Verwendungszweck)

Diese Implantat-Abutments werden direkt mit einem enossalen Implantat verbunden, um als Hilfsmittel bei der prothetischen Rehabilitation zu dienen. Der Implantataufbau beinhaltet eine wellenförmige Manschette, die den natürlichen Konturen des Weichgewebes folgt, und wird maßgefertigt, um den spezifischen Bedürfnissen des betreffenden Patienten zu entsprechen. Hergestellt aus Titan, Titanlegierung oder Zirkondioxid. Das Abutment wird mit einer Krone oder Brücke versorgt oder zur Verankerung eines Zahnersatzes verwendet.

2) Produktbeschreibung / Hauptspezifikationen

- Maßgefertigte, patientenspezifische Sonderanfertigung, hergestellt nach zahnärztlicher Verordnung und digitalen Eingabedaten.
- Konfiguration: Implantat-Abutments sind für die Verwendung im Oberkiefer oder Unterkiefer konzipiert, um einen Zahnersatz auf enossalen Implantaten zu stützen und dadurch die Kaufunktion des Patienten wiederherzustellen.
- Material: Titan/Zirkon

Zirkondioxid

3) Kontraindikationen

Nicht bei Patienten anwenden:

- die aus medizinischen Gründen nicht für dentale Implantatbehandlungen geeignet sind.
- mit einer bekannten Allergie oder Überempfindlichkeit gegen Reintitan oder Titanlegierungen.
- bei denen keine ausreichende Anzahl an Implantaten inseriert werden kann, um eine vollständige funktionelle Abstützung des Zahnersatzes zu gewährleisten.

4) Warnhinweise / Vorsichtsmaßnahmen / Potenzielle Risiken

DIESE ANWEISUNGEN SIND NICHT ALS ERSATZ FÜR EINE ANGEMESSENE SCHULUNGEN GEDACHT

⚠ WARNHINWEISE

- Für den sicheren und effektiven Einsatz von Zahnimplantaten wird dringend empfohlen, eine spezialisierte Ausbildung zu absolvieren, die auch praktische Schulungen zum Erlernen der korrekten Technik, der biomechanischen Anforderungen und der röntgenologischen Beurteilungen umfasst.
- Die Verantwortung für die richtige Patientenauswahl, eine angemessene Schulung, Erfahrung in der Implantatplatzierung sowie die Bereitstellung angemessener Informationen für die Einverständniserklärung liegt beim Behandler. Eine unsachgemäße Technik kann zum Implantatversagen, zur Schädigung von Nerven/Gefäßen und/oder zum Verlust von tragendem Knochen führen.

⚠ VORSICHTSMASSNAHMEN

- Sowohl neue als auch erfahrene Anwender von Implantaten sollten eine Schulung absolvieren, bevor sie ein neues System verwenden oder eine neue Behandlungsmethode anwenden.
- Besondere Vorsicht ist bei der Behandlung von Patienten geboten, die lokale oder systemische Faktoren haben, die die Heilung von Knochen und Weichgewebe beeinträchtigen könnten. (z. B. schlechte Mundhygiene, unkontrollierter Diabetes, Steroidtherapie, Raucher, Infektion im umliegenden Knochen und Patienten, die eine orofaziale Strahlentherapie hatten.)
- Falls zutreffend, das Provisorium entfernen.
- Bei Bedarf die Schraube überprüfen und nachziehen. Den Schraubenkanal mit Silikon verschließen und die endgültige „geschlossene“ Krone nach üblichen Verfahren einzementieren.
- Darauf achten, dass sämtliche Zementüberschüsse vom Rand entfernt werden.
- Ein zu starkes Anziehen des Abutments kann zum Bruch der Schraube führen.
- Die endgültige Krone oder das Gerüst nach dem Versiegeln des Zugangskanals unter Verwendung konventioneller Verfahren einzementieren und sicherstellen, dass keine Zementüberschüsse am Rand verbleiben.
- Bei verschraubtem Zahnersatz
- Der definitive Zahnersatz (Krone und Abutment) wird auf dem Implantat befestigt.
- Überprüfen des korrekten Sitzes
- Die Schraube mit dem erforderlichen Drehmoment festziehen. Das empfohlene Anzugsdrehmoment für die Abutmentschraube nicht überschreiten.

5) Reinigung und Pflege

Diese Abutments sind unsteril geliefert und sind für den Einmalgebrauch bestimmt.

6) Lagerung

- Das Produkt muss in einem trockenen, gut belüfteten Bereich bei Raumtemperatur gelagert und vor direkter Sonneneinstrahlung geschützt werden.
- Eine unsachgemäße Lagerung kann die Eigenschaften des Produkts beeinflussen.

7) Erwartete Lebensdauer / Nutzungsdauer

Ein Implantat-Abutment hält in der Regel 10 bis über 20 Jahre und entspricht oft der Lebensdauer der Krone, kann bei hervorragender Pflege jedoch auch länger halten; es überdauert meist die Krone (10–15 Jahre), ist jedoch weniger langlebig als der Implantatkörper. Die Langlebigkeit hängt vom Material, den Kaukräften (Molaren nutzen sich schneller ab) und Gewohnheiten wie Zähneknirschen (Bruxismus) ab. Dennoch sind eine gute Hygiene und regelmäßige Kontrolluntersuchungen der Schlüssel zur Maximierung der Lebensdauer, wobei einige Studien große Erfolge bei vollkeramischen Optionen zeigen.

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

- Müssen als biologischer oder medizinischer Abfall entsorgt werden, wenn sie im Mund eines Patienten verwendet wurden.
- Unbenutzte Abutments (Titan oder Zirkoniumoxid) können als normaler Abfall entsorgt werden.
- Richtlinien:
  - Benutzte Abutments:
    - Jeder Zahnersatz und jede Komponente, die sich im Mund des Patienten befunden hat, gilt als biologischer Abfall und muss gemäß den strengen Vorschriften für die Entsorgung medizinischer Abfälle gehandhabt und entsorgt werden.
  - Unbenutzte Abutments:
    - Wenn das maßgefertigte Abutment unbenutzt ist, nicht sterilisiert wurde und nicht mit Körperflüssigkeiten in Kontakt gekommen ist, fällt es möglicherweise nicht unter dieselben strengen Vorschriften für infektiösen Abfall.
- Material:
  - Titan/Zirkon: Die Materialien selbst (Titanlegierung, Zirkoniumoxid) sind in ihrer festen Form von Natur aus keine Gefahrstoffe, aber ihre Einstufung als Abfall wird durch ihre mögliche

biologische Kontamination während der Anwendung oder des Aufbereitungsprozesses bestimmt.

- Recycling:
  - Unabhängig von der grundsätzlichen Recycelbarkeit der Rohmaterialien ist die Entsorgung in der Zahnarztpraxis ausschließlich über zertifizierte Fachbetriebe für medizinische Abfälle abzuwickeln, um regulatorische Verstöße zu vermeiden.
- Befolgung örtlicher Vorschriften: Die Entsorgungsvorschriften unterliegen den bundes-, landes- und ortsspezifischen Gesundheits- und Umweltbestimmungen. Stellen Sie sicher, dass Ihre Praxis die spezifischen Anforderungen für Ihren Standort erfüllt.

UNIONE EUROPEA (ITALIANO)

ISTRUZIONI PER L'USO (IFU)

DISPOSITIVO PERSONALIZZATO UE (CMD = Dispositivo personalizzato)

GMDN / EMDN	P01020180: Dental Implants - Accessories
Codice(i) prodotto	TICLOCDES, TICLOCMED, TICLOCMEG, TICLOCNOB, TICLOCSTR, TICLOCZIM

Produttore:	**Zima International, Inc. Also DBA Dandy** 1320 N. 300 W., Lehi, UT 84043 United States
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	monouso

1) Destinazione d'uso (uso previsto)

Questi abutment dentali sono collegati direttamente a un impianto endosseo per essere utilizzati come ausilio nella riabilitazione protesica. L'abutment è progettato con una cuffia dentellata che ricopre i contorni naturali del tessuto molle ed è realizzato su misura per soddisfare le esigenze specifiche del paziente. Realizzato in titanio, lega di titanio o zirconia. L'abutment viene restaurato con una corona, un ponte oppure viene utilizzato per ancorare un dispositivo di restauro.

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: Gli abutment dentali sono progettati per essere utilizzati nella mascella o nella mandibola per supportare una protesi su impianti endossei, ripristinando così la funzione di masticazione per il paziente.
- Materiale: titanio/zirconia

Zirconia

3) Controindicazioni

Non usare in pazienti:

- Non idonei dal punto di vista medico alle procedure di impianto odontoiatrico.
- Allergici o con ipersensibilità al titanio puro o alla lega di titanio.
- In cui non è stato possibile posizionare un numero adeguato di impianti per ottenere il pieno supporto funzionale per una protesi.

4) Avvertenze / Precauzioni / Rischi potenziali

QUESTE ISTRUZIONI NON INTENDONO SOSTITUIRE UNA FORMAZIONE ADEGUATA

⚠ AVVERTENZE

- Per un uso sicuro ed efficace degli impianti dentali, si suggerisce vivamente di seguire una formazione specialistica, compresa una formazione pratica per imparare la tecnica corretta, i requisiti biomeccanici e le valutazioni radiografiche.
- La responsabilità della corretta selezione del paziente, della formazione adeguata, dell'esperienza nel posizionamento dell'impianto e della fornitura di informazioni adeguate per il consenso informato spetta al medico. Una tecnica impropria può causare la rottura dell'impianto, danni a nervi/vasi e/o la perdita dell'osso di supporto.

⚠ PRECAUZIONI

- Gli utenti di impianti nuovi ed esperti devono seguire una formazione prima di utilizzare un nuovo sistema o provare un nuovo metodo di trattamento.
- Prestare particolare attenzione quando si trattano pazienti con fattori locali o sistemici che potrebbero influenzare la guarigione dell'osso e del tessuto molle (ad es. scarsa igiene orale, diabete non controllato, in terapia steroidea, fumatori, infezione nell'osso vicino e pazienti sottoposti a radioterapia oro-facciale).
- Rimuovere il restauro temporaneo, se applicabile.
- Verificare e serrare nuovamente la vite, se applicabile. Sigillare il foro di accesso della vite con silicone e cementare la corona "chiusa" finale utilizzando le procedure convenzionali.
- Assicurarsi che tutto il cemento in eccesso venga rimosso dal margine.
- Il serraggio eccessivo dell'abutment può portare alla frattura della vite.
- Cementare la corona o la struttura finale usando le procedure convenzionali dopo aver sigillato il foro di accesso, assicurandosi che non ci sia cemento in eccesso sul margine.
- Per i restauri fissati con viti.
- Il restauro finale (corona e abutment) è fissato all'impianto.
- Verificare il posizionamento.
- Serrare la vite alla coppia richiesta. Non superare la coppia di serraggio raccomandata per la vite dell'abutment.

5) Pulizia e cura

Questi abutment non sono forniti sterili e sono monouso.

6) Conservazione

- Il prodotto deve essere conservato in un luogo asciutto e ben ventilato a temperatura ambiente e protetto dalla luce solare diretta.
- Una conservazione non corretta può influenzare le caratteristiche del dispositivo.

7) Durata prevista / Servizio

Un abutment dentale dura generalmente da 10 a 20 anni o più, spesso in linea con la durata della corona, ma può durare più a lungo con un'ottima cura; di solito supera la corona (10–15 anni), ma è meno resistente del supporto per impianto. La longevità dipende dal materiale, dalle forze di masticazione (i molari si usurano più velocemente) e dalle abitudini come il digrignamento (bruxismo). Tuttavia, una buona igiene e controlli regolari sono fondamentali per massimizzare la durata, con alcuni studi che mostrano grande successo con le opzioni tutte in ceramica.

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 tuo Stato membro, in conformità al Regolamento (UE) 2017/745 (MDR).

Autorità Competente:

- 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

- Se utilizzati nella bocca di un paziente, devono essere smaltiti come rifiuti biologici o medici.
- Gli abutment non utilizzati (titanio o zirconia) possono essere smaltiti come rifiuti generici.
- Linee guida:
  - Abutment usati:
    - Qualsiasi restauro dentale o componente presente nella bocca del paziente è considerato rifiuto biologico e deve essere manipolato e smaltito secondo le rigide normative sulla gestione dei rifiuti medici.
  - Abutment non utilizzati:
    - Se l'abutment personalizzato non viene utilizzato e non è stato sterilizzato o entra a contatto con fluidi corporei, potrebbe non rientrare nei casi previsti dalle stesse rigide normative in materia di rischio biologico.
- Materiale:
  - Titanio/zirconia: i materiali stessi (lega di titanio, zirconia) non sono materiali intrinsecamente pericolosi nella loro forma solida, ma la loro classificazione come rifiuti è determinata dalla loro potenziale contaminazione a rischio biologico durante l'uso o il processo di preparazione.
- Riciclaggio:
  - Mentre alcuni materiali sono riciclabili nei flussi generali di rifiuti di costruzione/demolizione, gli ambulatori dentistici devono utilizzare flussi di rifiuti medici certificati per evitare la non conformità normativa.
- Attenersi alle normative locali: le norme per lo smaltimento sono disciplinate dalle normative federali, statali e locali in materia di salute e ambiente. Assicurarsi che il proprio ambulatorio sia conforme ai requisiti specifici previsti per la sua sede.

UNITED KINGDOM (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

United Kingdom — Custom-Made Device (CMD)

GMDN / EMDN	63349
Product Code(s)	TICLOCDES, TICLOCMED, TICLOCMEG, TICLOCNOB, TICLOCSTR, TICLOCZIM

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)

These dental abutments are connected directly to an endosseous implant for use as an aid in prosthetic rehabilitation. The abutment is designed with a scalloped cuff that profiles the natural contours of soft tissue and is custom-made to meet your patient's specific needs. Made from titanium, titanium alloy, or Zirconia. The abutment gets restored with a crown, bridge, or is used to anchor a restorative device.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Dental abutments are designed to be used in the Maxilla or mandible to support a prosthesis on endosseous implants, thereby restoring chewing function for the patient.
- Material: Titanium/Zirconia

Zirconia

3) Contraindications

Do not use in patients:

- Those who are medically unfit for dental implant procedures.
- Those who are allergic or have hypersensitivity to pure titanium or titanium alloy.

- Those where adequate numbers of implants could not be placed to achieve full functional support for a prosthesis.

4) Warnings / Precautions / Potential Risks

THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING

⚠ WARNING

- For safe and effective use of dental implants, it is strongly suggested that specialised training be undertaken, including hands-on training to learn proper technique, biomechanical requirements, and radiographic evaluations.
- Responsibility for proper patient selection, adequate training, experience in implant placement, and providing appropriate information for informed consent rests with the practitioner. Improper technique can result in implant failure, damage to nerves/vessels, and/or loss of supporting bone.

⚠ CAUTION

- New and experienced Implant users should do training before using a new system or attempting a new treatment method.
- Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue. (e.g., poor oral hygiene, uncontrolled diabetes, are on steroid therapy, smokers, infection in the nearby bone, and patients who had oro-facial radiotherapy.)
- Remove the temporary restoration if applicable.
- Verify and re-tighten the screw if applicable. Seal the screw access hole with silicone and cement the final "closed" crown using conventional procedures.
- Make sure that all excess cement is removed from the margin.
- Overtightening of the abutment may lead to screw fracture)
- Cement the final crown or framework using conventional procedures after sealing the access hole, ensuring there's no excess cement on the margin.
- For screw retained restorations
- The final restoration (crown and abutment) is attached to the implant
- Verify the seating
- Tighten the screw to the required torque. (Do not exceed the recommended tightening torque for the abutment screw.

5) Cleaning and Care

These abutments are not supplied sterile and are intended for single use

6) Storage

The product must be stored in a dry, well-ventilated area at room temperature and protected from direct sunlight.

Incorrect storage may influence device characteristics

7) Expected Life / Service

A dental abutment typically lasts 10 to 20+ years, often aligning with the crown's lifespan, but can last longer with excellent care; it usually outlasts the crown (10-15 yrs) but is less durable than the implant post. Longevity depends on material, chewing forces (molars wear faster), and habits like grinding (bruxism). Still, good hygiene and regular checkups are key to maximizing its life, with some studies showing great success with all-ceramic options.

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

Must be disposed of as biological or medical waste if they have been used in a patient's mouth

Unused abutments (Titanium or Zirconia) may be disposed of as general waste

Guidelines:

Used Abutments:

Any dental restoration or component that has been in the patient's mouth is considered biological waste and must be handled and disposed of according to strict medical waste management regulations.

Unused Abutments:

If the custom abutment is unused and has not been sterilized or come into contact with bodily fluids, it may not fall under the same strict biohazard rules.

Material:

Titanium/Zirconia: The materials themselves (titanium alloy, zirconia) are not inherently hazardous materials in their solid form, but their classification as waste is determined by their potential biohazard contamination during use or the preparation process.

Recycling:

While some materials are recyclable in general construction/demolition waste streams, dental practices must use certified medical waste streams to avoid regulatory non-compliance.

Follow Local Regulations: Disposal rules are governed by federal, state, and local health and environmental regulations. Ensure your practice is compliant with the specific requirements for your location.

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

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

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

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

NOTE

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

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

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

Signatory Table

Action Name	User Name	Title	Signature Date
Approve	Kasha Lim	Supplier Quality Engineer	12-Jun-2026 01:47

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