

DECLARACIÓN UE DE CONFORMIDAD

EU DECLARATION OF CONFORMITY

FABRICANTE PRODUCTO
PRODUCT MANUFACTURER

MIMSAL TRADE S.L.

Dirección
Address

C. Mollet 17, Polígono Industrial Palou Nord
08401 Granollers (Barcelona)
Spain

DECLARAN BAJO SU RESPONSABILIDAD QUE EL PRODUCTO
DECLARE UNDER THEIR RESPONSIBILITY THAT THE PRODUCT

Nombre del producto - BASIC UDI-DI
Product name - BASIC UDI-DI

VISTA 843656286VISTAS4

Tipo
Type

**LUMINARIA CONLENTE DE AUMENTO
MAGNIFIER LAMP**

Referencia - Modelo - UDI-DI
Reference - Model - UDI-DI

E051CAO012 - VISTA PLUS H.F - 8436562860028
E051LAT212 - VISTA UV HANDLE H.F - 8436562860035

Finalidad prevista
Intended purpose

Lente convexa de aumento que concentra la luz eléctrica procedente de una fuente integrada, sobre los objetos visualizados
A convex lens with a built-in electrical light source intended to be used to concentrate light upon and magnify an object(s) being viewed

CUMPLE LOS REQUISITOS DEL REGLAMENTO (UE) 2017/745 SOBRE PRODUCTOS SANITARIOS
COMPLIES WITH THE REQUIREMENTS OF REGULATION (EU) 2017/745 ON MEDICAL DEVICES

Clasificación producto sanitario
Medical device classification



CLASE I - REGLA I
Class I - Rule I

Ensayos y medidas - Normas
Test and measurements - Standards

UNE-EN 60601-1:2008+/A12:2015 Part 1 Medical equipments
UNE-EN 60601-1-2:2015 Part 2 Medical equipments
UNE-EN 60601-2-41:2010+A11:2012+A1:2015

Accesorios
Accessories

B0101800 - WALL B SUPPORT 09651 - TROLLEY STAND 8,8 kg
B010190 - AH TABLE CLAMP B010150 - EXTENSION ARM
82026 - RAIL PLUS BRACKET

Lugar y fecha
Location and date

Granollers (Barcelona) España, a 11 de FEBRERO de 2022
Granollers (Barcelona) Spain, February 11th, 2022

Nombre y cargo
Name and position

Xavier Codina Jané
Director General
General Manager

Oriol Codina Miró
Responsable Técnico
Technical Manager

DÉCLARATION UE DE CONFORMITÉ

EU DECLARATION OF CONFORMITY

FABRICANT PRODUIT
PRODUCT MANUFACTURER

MIMSAL TRADE S.L.

Adresse
Address

C. Mollet 17, Polígono Industrial Palou Nord
08401 Granollers (Barcelona)
Spain

ATTESTENT SOUS LEUR SEULE RESPONSABILITÉ QUE LE PRODUIT
DECLARE UNDER THEIR RESPONSIBILITY THAT THE PRODUCT

Nom du produit - BASIC UDI-DI
Product name - BASIC UDI-DI

VISTA 843656286VISTA4

Type
Type

**LAMPE LOUPE
MAGNIFIER LAMP**

Référence - Modèle - UDI-DI
Reference - Model - UDI-DI

**E051CAO012 - VISTA PLUS H.F - 8436562860028
E051LAT212 - VISTA UV HANDLE H.F - 8436562860035**

Utilisation prévue
Intended purpose

**Lentille convexe munie d'une source lumineuse électrique intégrée, utilisée pour grossir la vue et concentrer la lumière sur un ou des objets à visualiser
A convex lens with a built-in electrical light source intended to be used to concentrate light upon and magnify an object(s) being viewed**

EST CONFORME AUX EXIGENCES DU RÈGLEMENT (UE) 2017/745 RELATIF AUX DISPOSITIFS MÉDICAUX
COMPLIES WITH THE REQUIREMENTS OF REGULATION (EU) 2017/745 ON MEDICAL DEVICES

Classification dispositif médical
Medical device classification



CLASSE I - RÈGLE I
Class I - Rule I

Tests et mesures - Normes
Test and measurements - Standards

**UNE-EN 60601-1:2008+/A12:2015 Part 1 Medical equipments
UNE-EN 60601-1-2:2015 Part 2 Medical equipments
UNE-EN 60601-2-41:2010+A11:2012+A1:2015**

Accessoires
Accessories

**B0101800 - WALL B SUPPORT 09651 - TROLLEY STAND 8,8 kg
B010190 - AH TABLE CLAMP B010150 - EXTENSION ARM
82026 - RAIL PLUS BRACKET**

Lieu et date
Location and date

**Granollers (Barcelona) Espagne, le 11 Février 2022
Granollers (Barcelona) Spain, February 11th, 2022**

Nom et fonction
Name and position

Xavier Codina Jané
Directeur général
General Manager

Oriol Codina Miró
Responsable technique
Technical Manager

DICHIARAZIONE UE DI CONFORMITÀ

EU DECLARATION OF CONFORMITY

FABBRICANTE PRODOTTO
PRODUCT MANUFACTURER

MIMSAL TRADE S.L.

Indirizzo
Address

C. Mollet 17, Polígono Industrial Palou Nord
08401 Granollers (Barcelona)
Spain

DICHIARA SOTTO LA PROPRIA RESPONSABILITÀ CHE IL PRODOTTO
DECLARE UNDER THEIR RESPONSIBILITY THAT THE PRODUCT

Nome del prodotto - BASIC UDI-DI
Product name - BASIC UDI-DI

VISTA 843656286VISTA4

Tipo
Type

**LAMPADA CONLENTE D'INGRANDIMENTO
MAGNIFIER LAMP**

Referenza - Modello - UDI-DI
Reference - Model - UDI-DI

**E051CAO012 - VISTA PLUS H.F - 8436562860028
E051LAT212 - VISTA UV HANDLE H.F - 8436562860035**

Finalità
Intended purpose

Lente convessa, provvista di una sorgente luminosa elettrica integrata, utilizzata per ingrandire la visione e concentrare la luce su uno o più oggetti osservati
A convex lens with a built-in electrical light source intended to be used to concentrate light upon and magnify an object(s) being viewed

SODDISFA I REQUISITI DEL REGOLAMENTO (UE) 2017/745 SUI DISPOSITIVI MEDICI
COMPLIES WITH THE REQUIREMENTS OF REGULATION (EU) 2017/745 ON MEDICAL DEVICES

Classificazione dispositivo medico
Medical device classification



CLASSE I - REGOLA I
Class I - Rule I

Prove e misurazioni - Norme
Test and measurements - Standards

UNE-EN 60601-1:2008+/A12:2015 Part 1 Medical equipments
UNE-EN 60601-1-2:2015 Part 2 Medical equipments
UNE-EN 60601-2-41:2010+A11:2012+A1:2015

Accessori
Accessories

B0101800 - WALL B SUPPORT 09651 - TROLLEY STAND 8,8 kg
B010190 - AH TABLE CLAMP B0101S0 - EXTENSION ARM
82026 - RAIL PLUS BRACKET

Data e luogo
Location and date

Granollers (Barcelona) Spagna, 11 FEBBRAIO 2022
Granollers (Barcelona) Spain, February 11th, 2022

Nome e carica
Name and position


Xavier Codina Jané
Direttore Generale
General Manager


Oriol Codina Miró
Responsabile Tecnico
Technical Manager

DECLARAÇÃO UE DE CONFORMIDADE

EU DECLARATION OF CONFORMITY

FABRICANTE DO PRODUTO
PRODUCT MANUFACTURER

MIMSAL TRADE S.L.

Endereço
Address

C. Mollet 17, Polígono Industrial Palou Nord
08401 Granollers (Barcelona)
Spain

DECLARAM SOB SUA RESPONSABILIDADE QUE O PRODUTO
DECLARE UNDER THEIR RESPONSIBILITY THAT THE PRODUCT

Nome do produto - BASIC UDI-DI
Product name - BASIC UDI-DI

VISTA 843656286VISTA4

Tipo
Type

**LUMINÁRIA COM LENTE DE AUMENTO
MAGNIFIER LAMP**

Referência - Modelo - UDI-DI
Reference - Model - UDI-DI

**E051CAO012 - VISTA PLUS H.F - 8436562860028
E051LAT212 - VISTA UV HANDLE H.F - 8436562860035**

Finalidade Prevista
Intended purpose

Lente convexa com uma fonte luz eléctrica integrada utilizada para ampliar a visão e concentrar a luz sobre um ou mais objectos alvo de visualização
A convex lens with a built-in electrical light source intended to be used to concentrate light upon and magnify an object(s) being viewed

CUMPRE OS REQUISITOS DO REGULAMENTO (UE) 2017/745 RELATIVO AOS DISPOSITIVOS MÉDICOS
COMPLIES WITH THE REQUIREMENTS OF REGULATION (EU) 2017/745 ON MEDICAL DEVICES

Classificação do dispositivo médico
Medical device classification



CLASSE I - REGRA I
Class I - Rule I

Ensaios e medidas - Normas
Test and measurements - Standards

**UNE-EN 60601-1:2008+/A12:2015 Part 1 Medical equipments
UNE-EN 60601-1-2:2015 Part 2 Medical equipments
UNE-EN 60601-2-41:2010+A11:2012+A1:2015**

Acessórios
Accessories

**B0101800 - WALL B SUPPORT 09651 - TROLLEY STAND 8,8 kg
B010190 - AH TABLE CLAMP B010150 - EXTENSION ARM
82026 - RAIL PLUS BRACKET**

Local e data
Location and date

Granollers (Barcelona) Espanha, a 11 de FEVEREIRO de 2022
Granollers (Barcelona) Spain, February 11th, 2022

Nome e cargo
Name and position

Xavier Codina Jané
Diretor-Geral
General Manager

Oriol Codina Miró
Responsável Técnico
Technical Manager

EU-KONFORMITÄTSERKLÄRUNG

EU DECLARATION OF CONFORMITY

DER HERSTELLER DES PRODUKTS
PRODUCT MANUFACTURER

MIMSAL TRADE S.L.

Adresse
Address

C. Mollet 17, Polígono Industrial Palou Nord
08401 Granollers (Barcelona)
Spain

ERKLÄRT IN EIGENER VERANTWORTUNG, DASS DAS PRODUKT
DECLARE UNDER THEIR RESPONSIBILITY THAT THE PRODUCT

Produktname - BASIC UDI-DI
Product name - BASIC UDI-DI

VISTA 843656286VISTA S4

Type
Type

LAMPE MIT VERGRÖSSERUNGSLUPE
MAGNIFIER LAMP

Referenz - Modell - UDI-DI
Reference - Model - UDI-DI

E051CAO012 - VISTA PLUS H.F - 8436562860028
E051LAT212 - VISTA UV HANDLE H.F - 8436562860035

Verwendungszweck
Intended purpose

Konvexe Linse mit integrierter elektrischer Lichtquelle zur optischen Vergrößerung und zur Konzentration von Licht auf die betrachteten Objekte
A convex lens with a built-in electrical light source intended to be used to concentrate light upon and magnify an object(s) being viewed

ERFÜLLT DIE ANFORDERUNGEN DER VERORDNUNG (EU) 2017/745 ÜBER MEDIZINPRODUKTE
COMPLIES WITH THE REQUIREMENTS OF REGULATION (EU) 2017/745 ON MEDICAL DEVICES

Klassifizierung von Medizinprodukten
Medical device classification



KLASSE I - VORSCHRIFT I
Class I - Rule I

Prüfungen und Messungen - Normen
Test and measurements - Standards

UNE-EN 60601-1:2008+/A12:2015 Part 1 Medical equipments
UNE-EN 60601-1-2:2015 Part 2 Medical equipments
UNE-EN 60601-2-41:2010+A11:2012+A1:2015

Zubehör
Accessories

B0101800 - WALL B SUPPORT 09651 - TROLLEY STAND 8,8 kg
B010190 - AH TABLE CLAMP B010150 - EXTENSION ARM
82026 - RAIL PLUS BRACKET

Ort und Datum
Location and date

Granollers (Barcelona) Spanien, den 11. FEBRUAR 2022
Granollers (Barcelona) Spain, February 11th, 2022

Name und Titel
Name and position


Xavier Codina Jané
General Manager
General Manager


Oriol Codina Miró
Technischer Leiter
Technical Manager