

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 CON LENTE DE AUMENTO
MAGNIFIER LAMP

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

E051L - VISTA LED HANDLE - 8436562860462
E051PL - VISTA LED PLUS - 8436562860479

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 1 de ENERO de 2022
Granollers (Barcelona) Spain, January 1st, 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  843656286VISTAS4

Type
Type

LAMPE LOUPE
MAGNIFIER LAMP

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

E051L - VISTA LED HANDLE - 8436562860462
E051PL - VISTA LED PLUS - 8436562860479

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 B0101S0 - EXTENSION ARM
82026 - RAIL PLUS BRACKET

Lieu et date
Location and date

Granollers (Barcelona) Espagne, le 1 Janvier 2022
Granollers (Barcelona) Spain, January 1st, 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 **UDI** 843656286VISTA4

Tipo
Type

LAMPADA CON LENTE D'INGRANDIMENTO
MAGNIFIER LAMP

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

E051L - VISTA LED HANDLE - 8436562860462
E051PL - VISTA LED PLUS - 8436562860479

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

CE 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 B010150 - EXTENSION ARM
82026 - RAIL PLUS BRACKET

Data e luogo
Location and date

Granollers (Barcelona) Spagna, 1 GENNAIO 2022
Granollers (Barcelona) Spain, January 1st, 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  843656286VISTAS4

Tipo
Type

LUMINÁRIA COM LENTE DE AUMENTO
MAGNIFIER LAMP

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

E051L - VISTA LED HANDLE - 8436562860462
E051PL - VISTA LED PLUS - 8436562860479

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

Ensaio 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 B0101S0 - EXTENSION ARM
82026 - RAIL PLUS BRACKET

Local e data
Location and date

Granollers (Barcelona) Espanha, a 1 de JANEIRO de 2022
Granollers (Barcelona) Spain, January 1st, 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  843656286VISTAS4

Type
Type

LAMPE MIT VERGRÖßERUNGSLUPE
MAGNIFIER LAMP

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

E051L - VISTA LED HANDLE - 8436562860462
E051PL - VISTA LED PLUS - 8436562860479

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 B0101S0 - EXTENSION ARM
82026 - RAIL PLUS BRACKET

Ort und Datum
Location and date

Granollers (Barcelona) Spanien, den 1. JANUAR 2022
Granollers (Barcelona) Spain, January 1st, 2022

Name und Titel
Name and position


Xavier Codina Jané
General Manager
General Manager


Oriol Codina Miró
Technischer Leiter
Technical Manager