

# DECLARACIÓN UE DE CONFORMIDAD

## EU DECLARATION OF CONFORMITY

FABRICANTE PRODUCTO  
PRODUCT MANUFACTURER

Dirección  
Address

MIMSAL TRADE S.L.

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

**MS 843656286MSZJ**

Tipo  
Type

**LÁMPARA DE RECONOCIMIENTO  
EXAMINATION LAMP**

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

M187001C - MS CEILING PLUS - 8436562860493  
M183500C - MS CEILING - 8436562860486  
M187001 - MS LED PLUS - 8436562860394  
M183500 - MS LED - 8436562860387  
M187001FL - MS FLEX PLUS - 8436562860431  
M183500FL - MS FLEX - 8436562860424

Finalidad prevista  
Intended purpose

Dispositivo para iluminar el lugar de exploración del paciente  
Device intended to provide light to illuminate a site of patient examination

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

**CE 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

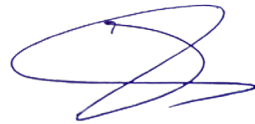
B0101800 - WALL B SUPPORT 09651 - TROLLEY STAND 8,8 kg  
B010190 - AH TABLE CLAMP B010150 - EXTENSION ARM  
82026 - RAIL PLUS BRACKET

Lugar y fecha  
Location and date

Granollers (Barcelona) España, a 16 de ENERO de 2023  
Granollers (Barcelona) Spain, January 16th, 2023

Nombre y cargo  
Name and position

  
Roger Codina Miró  
Director General  
General Manager

  
Jorge García González  
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

**MS 843656286MSZJ**

Type  
Type

**LAMPE D'EXAMEN**  
**EXAMINATION LAMP**

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

M187001C - MS CEILING PLUS - 8436562860493  
M183500C - MS CEILING - 8436562860486  
M187001 - MS LED PLUS - 8436562860394  
M183500 - MS LED - 8436562860387  
M187001FL - MS FLEX PLUS - 8436562860431  
M183500FL - MS FLEX - 8436562860424

Utilisation prévue  
Intended purpose

Dispositif destiné à éclairer le site d'examen du patient  
Device intended to provide light to illuminate a site of patient examination

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

**CE 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

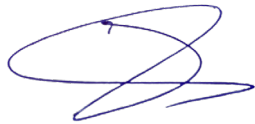
B0101800 - WALL B SUPPORT 09651 - TROLLEY STAND 8,8 kg  
B010190 - AH TABLE CLAMP B0101S0 - EXTENSION ARM  
82026 - RAIL PLUS BRACKET

Lieu et date  
Location and date

Granollers (Barcelona) Espagne, le 16 Janvier 2023  
Granollers (Barcelona) Spain, January 16th, 2023

Nom et fonction  
Name and position

  
**Roger Codina Miró**  
Directeur général  
General Manager

  
**Jorge García González**  
Responsable Technique  
Technical Manager

# DICHIARAZIONE UE DI CONFORMITÀ

## EU DECLARATION OF CONFORMITY

FABBRICANTE PRODOTTO  
PRODUCT MANUFACTURER

Indirizzo  
Address

MIMSAL TRADE S.L.

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

**MS 843656286MSZJ**

Tipo  
Type

**LAMPADA DA VISITA  
EXAMINATION LAMP**

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

M187001C - MS CEILING PLUS - 8436562860493  
M183500C - MS CEILING - 8436562860486  
M187001 - MS LED PLUS - 8436562860394  
M183500 - MS LED - 8436562860387  
M187001FL - MS FLEX PLUS - 8436562860431  
M183500FL - MS FLEX - 8436562860424

Finalità  
Intended purpose

Dispositivo concepito per fornire la luce necessaria per illuminare la sede di visita del paziente  
Device intended to provide light to illuminate a site of patient examination

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

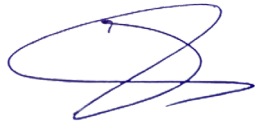
B0101800 - WALL B SUPPORT 09651 - TROLLEY STAND 8,8 kg  
B010190 - AH TABLE CLAMP B0101S0 - EXTENSION ARM  
82026 - RAIL PLUS BRACKET

Data e luogo  
Location and date

Granollers (Barcelona) Spagna, 16 GENNAIO 2023  
Granollers (Barcelona) Spain, January 16th, 2023

Nome e carica  
Name and position

  
Roger Codina Miró  
Direttore Generale  
General Manager

  
Jorge García González  
Responsabile Tecnico  
Technical Manager

# DECLARAÇÃO UE DE CONFORMIDADE

## EU DECLARATION OF CONFORMITY

FABRICANTE DO PRODUTO  
PRODUCT MANUFACTURER

Endereço  
Address

MIMSAL TRADE S.L.

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

**MS 843656286MSZJ**

Tipo  
Type

**LÂMPADA DE RECONHECIMENTO  
EXAMINATION LAMP**

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

M187001C - MS CEILING PLUS - 8436562860493  
M183500C - MS CEILING - 8436562860486  
M187001 - MS LED PLUS - 8436562860394  
M183500 - MS LED - 8436562860387  
M187001FL - MS FLEX PLUS - 8436562860431  
M183500FL - MS FLEX - 8436562860424

Finalidade Prevista  
Intended purpose

Dispositivo destinado a iluminar o local de exame do doente  
Device intended to provide light to illuminate a site of patient examination

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 16 de JANEIRO De 2023  
Granollers (Barcelona) Spain, January 16th, 2023

Nome e cargo  
Name and position

  
Roger Codina Miró  
Diretor-Geral  
General Manager

  
Jorge García González  
Responsável Técnico  
Technical Manager

# EU-KONFORMITÄTSERKLÄRUNG

## EU DECLARATION OF CONFORMITY

DER HERSTELLER DES PRODUKTS  
PRODUCT MANUFACTURER

Adresse  
Address

MIMSAL TRADE S.L.

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

**MS 843656286MSZJ**

Type  
Type

**UNTERSUCHUNGSLAMPE**  
**EXAMINATION LAMP**

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

M187001C - MS CEILING PLUS - 8436562860493  
M183500C - MS CEILING - 8436562860486  
M187001 - MS LED PLUS - 8436562860394  
M183500 - MS LED - 8436562860387  
M187001FL - MS FLEX PLUS - 8436562860431  
M183500FL - MS FLEX - 8436562860424

Verwendungszweck  
Intended purpose

Vorrichtung zur Beleuchtung des Untersuchungs- am Patienten  
Device intended to provide light to illuminate a site of patient examination

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 16. JANUAR 2023  
Granollers (Barcelona) Spain, January 16th, 2023

Name und Titel  
Name and position

  
Roger Codina Miró  
General Manager  
General Manager

  
Jorge García González  
Technischer Leiter  
Technical Manager