

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

LUXIFLEX 843656286LUXTK

Tipo
Type

**LÁMPARA DE RECONOCIMIENTO
EXAMINATION LAMP**

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

I0104NL - LUXIFLEX LED PLUS - 8436562860356
I0104AOLED - LUXIFLEX LED - 8436562860011
I0104NLSR - LUXIFLEX SENSOR PLUS - 8436562860417
I0104AOLEDSR - LUXIFLEX SENSOR - 8436562860400
I0104AO - LUXIFLEX HAL - 8436562860004

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 09655 - TROLLEY STAND 4 kg
82026 - RAIL PLUS BRACKET B0101S0 - EXTENSION ARM

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

LUXIFLEX 843656286LUXTK

Type
Type

LAMPE D'EXAMEN
EXAMINATION LAMP

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

I0104NL - LUXIFLEX LED PLUS - 8436562860356
I0104AOLED - LUXIFLEX LED - 8436562860011
I0104NLSR - LUXIFLEX SENSOR PLUS - 8436562860417
I0104AOLEDSR - LUXIFLEX SENSOR - 8436562860400
I0104AO - LUXIFLEX HAL - 8436562860004

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 09655 - TROLLEY STAND 4 kg
82026 - RAIL PLUS BRACKET B0101S0 - EXTENSION ARM

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

LUXIFLEX 843656286LUXTK

Tipo
Type

**LAMPADA DA VISITA
EXAMINATION LAMP**

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

I0104NL - LUXIFLEX LED PLUS - 8436562860356
I0104AOLED - LUXIFLEX LED - 8436562860011
I0104NLSR - LUXIFLEX SENSOR PLUS - 8436562860417
I0104AOLEDSR - LUXIFLEX SENSOR - 8436562860400
I0104AO - LUXIFLEX HAL - 8436562860004

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	09655 - TROLLEY STAND 4 kg
82026 - RAIL PLUS BRACKET	B0101S0 - EXTENSION ARM

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

LUXIFLEX 843656286LUXTK

Tipo
Type

**LÂMPADA DE RECONHECIMENTO
EXAMINATION LAMP**

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

I0104NL - LUXIFLEX LED PLUS - 8436562860356
I0104AOLED - LUXIFLEX LED - 8436562860011
I0104NLSR - LUXIFLEX SENSOR PLUS - 8436562860417
I0104AOLEDSR - LUXIFLEX SENSOR - 8436562860400
I0104AO - LUXIFLEX HAL - 8436562860004

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 09655 - TROLLEY STAND 4 kg
82026 - RAIL PLUS BRACKET B0101S0 - EXTENSION ARM

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

LUXIFLEX 843656286LUXTK

Type
Type

UNTERSUCHUNGSLAMPE
EXAMINATION LAMP

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

I0104NL - LUXIFLEX LED PLUS - 8436562860356
I0104AOLED - LUXIFLEX LED - 8436562860011
I0104 NLSR - LUXIFLEX SENSOR PLUS - 8436562860417
I0104AOLED SR - LUXIFLEX SENSOR - 8436562860400
I0104AO - LUXIFLEX HAL - 8436562860004

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	09655 - TROLLEY STAND 4 kg
82026 - RAIL PLUS BRACKET	B0101S0 - EXTENSION ARM

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