

# DECLARACIÓN DE CONFORMIDAD DECLARATION OF CONFORMITY

Nº 20210201

FABRICANTE:  
MANUFACTURER:

ORDISI s.a

DIRECCIÓN:  
ADDRESS

Tecnologia 2, nave 7  
08780 Pallejà, Barcelona, Spain

SRN:

ES-MF-00000987

DECLARAN BAJO SU EXCLUSIVA RESPONSABILIDAD QUE EL/LOS PRODUCTO(S) FABRICADO(S):  
DECLARE UNDER THEIR SOLE RESPONSIBILITY THAT THE MANUFACTURED PRODUCT(S):

**Nombre /Name** Lámpara de reconocimiento FLH-2 series  
**UDI DI básico/UDI DI** 84352050FLH2L4  
**REF/REF:**

FLH2131	LAMPARA FLH-2 A LEDS RODABLE / Moveable lamp FLH-2 model with LED
FLH2131L	LAMPARA FLH-2 A LED RODABLE BRAZO 700 + 200 / Moveable lamp FLH-2 model with LED - Arm 700+200
FLH2135	LAMPARA FLH-2 A LEDS RODABLE CON SENSOR IR / Moveable lamp FLH-2 model with LED and IR sensor switch
FLH2135L	LAMPARA FLH-2 A LEDS RODABLE CON SENSOR IR Y BRAZO 700 + 200 MM / Moveable lamp FLH-2 model with LED and IR sensor switch, Arm 700+200
FLH2231	FLH-2 A LED CON SOPORTE A MESA / Lamp FLH-2 model with LED and table stand
FLH2231L	FLH-2 A LED CON SOPORTE A MESA BRAZO 700+200 / Lamp FLH-2 model with LED and table stand - Arm 700+200
FLH2235	FLH-2 A LED CON SOPORTE A MESA CON SENSOR IR / Lamp FLH-2 model with LED, table stand, IR sensor switch
FLH2235L	FLH-2 A LED CON SOPORTE A MESA CON SENSOR IR Y BRAZO 700 + 200 MM / Lamp FLH-2 model with LED, table stand, IR sensor switch, Arm 700+200
FLH2331	FLH-2 A LED CON SOPORTE PARED / Wall lamp FLH-2 model with LED
FLH2331L	FLH-2 A LED CON SOPORTE A PARED BRAZO 700+200 / Wall lamp FLH-2 model with LED bulb - Arm 700+200
FLH2335	FLH-2 A LED CON SOPORTE PARED CON SENSOR IR / Wall lamp FLH-2 model with LED and IR sensor switch
FLH2335LC	FLH-2 A LED CON SOPORTE PARED CON SENSOR IR, BRAZO LARGO CURVO / Wall lamp FLH-2 model LED and IR sensor switch, arm longer and curve
FLH233Z	FLH-2 LED CON SOPORTE A PARED ESPECIAL 900+450 / Wall lamp FLH-2 model with LED bulb - Special arm 900+450
FLH2431	FLH-2 A LED CON SOPORTE A RAIL / Lamp FLH-2 model w/rail holder with LED bulb
FLH2431L	FLH-2 A LED CON SOPORTE RAIL BRAZO 700+200 / Lamp FLH-2 model w/rail holder with LED bulb - Arm 700+200
FLH2431V	FLH-2 A LED CON SOPORTE A RAIL VERTICAL / Lamp FLH-2 model w/vertical rail holder with LED bulb
FLH2435	FLH-2 A LED CON SOPORTE A RAIL Y SENSOR IR / Lamp FLH-2 model w/rail holder with LED bulb and IR sensor switch
FLH2435L	FLH-2 A LED CON SOPORTE A RAIL Y SENSOR IR BRAZO 700 + 200 / Lamp FLH-2 LED model w/rail holder, IR sensor switch and arm 700+200
FLH2531	FLH-2 A LED PARA SILLAS GINECOLOGICAS / Lamp FLH-2 to LED for gynaecology chair
FLH2631	LAMPARA FLH-2 A LED / Lamp FLH-2 model with LED
FLH2731	FLH-2 A LED A RAIL / Lamp FLH-2 model to rail with LED bulb
FLH2731W	FLH-2 A LED A PARED / Lamp FLH-2 model with LED bulb wall mounted

**Finalidad Prevista** Dispositivo destinado a iluminar el lugar de tratamiento y/o examen del paciente.  
**Intended Use** Device intended to provide light to illuminate a site of patient examination and/or treatment.

**Clasificación:** I (anexo VIII regla 13)  
**Classification:** (annex VIII rule 13)

1. CUMPLEN LOS REQUISITOS ESENCIALES Y DISPOSICIONES DE LOS REGLAMENTOS:  
CONFORMS WITH THE ESSENTIAL REQUIREMENTS AND PROVISIONS OF THE REGULATIONS:

**(EU) 2017/745**  
y sus modificaciones / as amended

MDR Sobre productos sanitarios,  
Medical Devices Regulations,  
y su transposición a la legislación nacional  
as transposed into national law

**Ruta evaluación conformidad:** Declaración de conformidad (Annex IV)  
**Conformity assessment route** Declaration of conformity (Annex IV)

**Expediente Técnico / :** TF-FLH2SERIES  
**Technical documentation**

**Normas armonizadas/Harmonized standards:** EN60601-2-41:2010; EN60601-1:2006/A12:2015 EN60601-1-2:2015; ISO 14971:2019/A11:2021; ISO 15223-1:2021; EN60601-1-6:2010; EN62366-1:2015

**Sistema de Calidad según/Quality system according:** EN ISO 13485:2016/A11:2021; EN ISO 9001:2015.

**LUGAR Y FECHA / Place and date:**

Pallejà 10 / march / 2022

**Nombre y Firma**  
**Name and Signature**



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