

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
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/AC:2010 EN60601-1-2:2015; ISO 14971:2012; ISO15223-1:2006; EN60601-1-6:2010; EN62366:2008

Sistema de Calidad según/Quality system according: EN ISO 13485:2016 + /AC:2018; EN ISO 9001:2015.

LUGAR Y FECHA / Place and date:

Pallejà 10 / march / 2022

Nombre y Firma
Name and Signature



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Marc Pallarès
Técnico Responsable
Regulatory Responsible

Joan B. Boix
Director General
General Manager