

CE EU Declaration of Conformity

The devices covered by the present declaration are in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices (MDR).

Manufacturer Dr. Mach GmbH & Co. KG
Am Brucker Feld 4
85567 Grafing, GERMANY

SRN DE-MF-000008787

Products Examination lights
Operating theater (OT) lights
Video systems
Device carriers

Models/Basic UDI-DI See Annex I

Intended Use The Examination lights and Operating theatre lights are designed to illuminate an examination or surgical site (e.g. in a laboratory, a hospital or in a doctor's practice) with focused, low-glare and shadow-free light. They enable the user to perform a diagnosis or carry out medical interventions.

The Video systems are intended to record a video image of an examination or operating site (e.g. in a laboratory, a hospital or in a doctor's practice) and to make it available as a video signal via a standardized interface. The video signal can be used for medical training or further education and for documentation.

The Device carriers are intended to carry instruments / devices and supply facilities (sockets etc.) or screens / touchscreens in the vicinity of an examination or operating theater (e.g. in a laboratory, a hospital or in a doctor's practice) and to position them spatially.

Classification Examination lights and Operating theater lights are active class I medical devices in accordance with Annex VIII, Rule 10 of the regulation. Video systems and Device carriers are active class I medical devices in accordance with Annex VIII, Rule 13 of the regulation.

The marking is performed by the symbol: 

Standards EN 60601-1:2006 + Cor.:2010 + A1:2013 + AC:2014 + A1:2013/AC:2014 + A12:2014 + A2:2021
EN 60601-1-2:2015 + A1:2021
EN 60601-2-41:2009 + A1:2015

I, the undersigned, hereby certify that all products listed here comply with the General Safety and Performance Requirements set out in Annex I of the Regulation (MDR).

This declaration of conformity is issued under the sole responsibility of Dr. Mach GmbH & Co. KG.

Signed for and on behalf of the manufacturer:

Dr. Mach GmbH & Co. KG

Signature:



Name:

Dr. Michael Suhre

Function:

CIO

Location:

Grafing

Date:

2023-09-20

Annex I

Model / Variant	Basic UDI-DI	Model / Variant	Basic UDI-DI
Mach LED 2	426018944MachLED2QR	Mach LED 110	426018944MachLED1105B
Mach LED 2MC		Mach LED 115	426018944MachLED1155M
Mach LED 2SC		Mach LED 115	
Mach LED 2SC Hybrid		Mach LED 115C	
Mach LED 2 Smart		Mach LED 120	426018944MachLED1205E
Mach LED 3	426018944MachLED3QT	Mach LED 120	
Mach LED 3MC		Mach LED 120F	
Mach LED 3SC		Mach LED 130	426018944MachLED1305H
Mach LED 3 Smart		Mach LED 130	
Mach LED 5	426018944MachLED5QX	Mach LED 130F	
Mach LED 5MC		Mach LED 130 Plus	
Mach LED 5SC		Mach LED 130 Dental	
Mach LED 5 Smart		Mach LED 130 Dental P	
Mach LED 6MC	420618944MachLED6MC8M	YLED-1F	426018944YLED-1FH8
Mach LED 6MC DF		Video systems	426018944MachVideo2C
Mach LED 6MC F		Videosystem HDMV	
Mach LED 6MC DF S		Videosystem HDMV-F	
Mach LED 6MC F S		Videosystem HDMV-F 4K	
Mach LED 6MC DF KV		Device carriers	426018944MachUtilityWM
Mach LED 6MC F KV		Monitor holder	
Mach LED 6MC DF S KV		Camera holder	
Mach LED 6MC F S KV		Socket holder	
Mach LED 8MC	426018944MachLED8MCA3	Tray table	
Mach LED 8MC DF			
Mach LED 8MC F			
Mach LED 8MC DF S			
Mach LED 8MC F S			
Mach LED 8MC DF KV			
Mach LED 8MC F KV			
Mach LED 8MC DF S KV			
Mach LED 8MC F S KV			
Mach LED 150	426018944MachLED1505P		
Mach LED 150			
Mach LED 150F			
Mach LED 150FP			
Mach LED 150MC			
Mach LED 150MC P			
Mach LED 300	426018944MachLED3005J		
Mach LED 300DF SC			
Mach LED 300DF SC Spot			
Mach LED 300MC			