

CE EC - Declaration of Conformity

In accordance with Annex I and VII of the EC Directive 93/42/EEC concerning medical devices, last amended by Directive 2007/47/EC of 5 September 2007

Manufacturer: Dr. Mach GmbH & Co. KG
Flossmannstraße 28
D-85560 Ebersberg (Germany)

the undersigned herewith confirms under his own responsibility that the products listed below

Type designation: Mach 130, Mach 130F, Uniflex
Mach LED 110
Mach LED 115, Mach LED 115C
Mach LED 120, Mach LED 120F
Mach LED 130, Mach LED 130F, Mach LED 130 Plus
Mach LED 130 Dental, Mach LED 130 Dental P
Mach LED 150, Mach LED 150F, Mach LED 150FP
Mach LED 300 DF
Mach LED 2MC, Mach LED 2SC, Mach LED 2SC Hybrid
Mach LED 2 Smart
Mach LED 3MC, Mach LED 3SC
Mach LED 3 Smart
Mach LED 5MC, Mach LED 5SC
Mach LED 5 Smart

Instrument and equipment racks with double sockets and PA sockets
VDU support
Doctor's instrument table, hand operating table

Video system MFB-MO
Video system Mach HD
Wireless – HRC
Wireless – SRC
Wireless – CRC

complies with the basic requirements and provisions of the following directive:

Directive **93/42/EEC**, Annex I of the Council of 14 June 1993 concerning medical devices

Standards: EN 60601-1 : 2013 (IEC 60601-1)
EN 60601-1 : 2006 (IEC 60601-1)
EN 60601-2-41 : 2010 (IEC 60601-2-41)
EN 60601-2-41 : 2016-02 (IEC 60601-2-41)
EN 60601-1-2 :2007
EN 60601-1-2 :2015

Class: The examination and/or operating lamps and their accessories are Class I active medical products according to Annex IX of the Directive

Labeling is by means of the mark: **CE**

This certificate is valid until: September 05th 2022

Ebersberg
Town

September 5th 2017
Date


Dr. Peter Kohrs
Technical Manager