

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 LED 6MC F
Mach LED 6MC DF
Mach LED 6MC F S
Mach LED 6MC DF S
Mach LED 6MC F KV
Mach LED 6MC DF KV
Mach LED 6MC DF S KV
Mach LED 6MC DF S KV
Mach LED 6MC DF S KV
Mach LED 8MC F
Mach LED 8MC F
Mach LED 8MC F S

Mach LED 8MC F S
Mach LED 8MC DF S
Mach LED 8MC DF KV
Mach LED 8MC DF KV
Mach LED 8MC F S KV
Mach LED 8MC DF S KV
Mach LED 300DF SC
Mach LED 300DF SC Spot
Mach LED 300MC
Videosystem HDMV-F 4K

comply 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 60601-2-41:2016-02 (IEC 60601-2-41)

EN 60601-1-2:2015

Class:

The products are class I active medical devices according to Annex IX of the

Directive

Labeling is by means of the mark: (€

This certificate is valid until:

February 26th 2026

Ebersberg Town February 26th 2021

Date

Dr. Peter Kohrs
Technical Manager

Signature