

Bülach, March 2023

# Self-declaration

## WIEGAND® MediCups article no. 71.1, 71.2, 71.3, 71.4 and 71.5

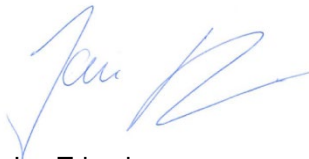
We hereby confirm that the WIEGAND® MediCups with article no. 71.1, 71.2, 71.3, 71.4 and 71.5 comply with the Medical Device Directive 93/42/EEC and the Medical Device Regulation EU MDR 2017/745. The articles are marked with the CE symbol and have been regularly tested and certified by an independent institute.

### Certificate

All certificates concerning the WIEGAND® MediCups with article no. 71.1, 71.2, 71.3, 71.4 as well as 71.5 were commissioned directly by the manufacturer and issued in his name. The certificates are valid and applicable for the mentioned WIEGAND® MediCups. Valid certificates of the mentioned products are available on request from Wiegand AG.

### Food-safe products

The requirements for food safety are covered for medical devices in both the Medical Devices Directive 93/42/EEC and the Medical Devices Regulation EU MDR 2017/745. They fall under the essential requirements defined in Annex I of both the Medical Devices Directive (Annex I, 7.1 and 7.3) and the Medical Devices Regulation (Annex I, 10.1 and 10.3). The technical documentation (Ref: TF-MB-06-MDD) of the WIEGAND® MediBecher takes this requirement into account and also fulfils it.



Jan Trimpin

Managing Director  
Wiegand AG