

Declaration of Conformity acc. to Annex IV of the Regulation 2017/746 on IVD medical devices (IVDR)



Dr. Müller Gerätebau GmbH SRN: DE-MF-000024467 Burgker Straße 133 01705 Freital Germany

We, company Dr. Müller Gerätebau GmbH, declare that the issuing of this Declaration of Conformity is our sole responsibility.

| Product name | REF. No. | Basic UDI-DI | Intended use | Risk class |
|--------------------------------------|------------------|---------------------|-----------------------------|---------------|
| SensoStar GL 30 touch SensoStar G | 920118 920115 | 42555893500AA1000R4 | electrochemical analyser | Α |

We hereby declare that listed product complies with all applicable requirements of EU Regulation 2017/746 on IVD medical devices (IVDR). The above-mentioned product is an in vitro diagnostic medical device according to article 2(2) of the IVDR.

It fulfils the basic safety and performance requirements according to Annex I of the IVDR.

Conformity has been established by conformity assessment procedure after drawing up the technical documentation set out in Annexes II and III of the IVDR.

This Declaration of Conformity is valid from serial number 2005 (SensoStar GL 30 touch) and 0296 (SensoStar G).

Freital, August 11, 2022

Matthias Hartwig

Managing Director / CEO
Dr. Müller Gerätebau GmbH

08/2022 Rev. 00