SARTORIUS

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Manufacturer's Declaration

The Sartorius Lab Instruments GmbH & Co. KG in Goettingen, Germany, is a manufacturing plant certified for compliance with DIN EN ISO 9001:2015 and DIN EN ISO 14001:2015 by the German Association for Certification of Management Systems (DQS).

Additionally, our management system has received the following certification and accreditation:

- DIN EN ISO/IEC 17020: Int. Standard for Conformity assessment – Requirements for the operation of various types of bodies performing inspection
  - Inspection body D-IS-19398-01
- DIN EN ISO/IEC 17025: Int. Standard for General requirements for the competence of testing and calibration laboratories
  - Calibration Laboratory D-K-19398-01 for Conventional Mass (Weights), Weighing Instruments and Volume
- EC Directive 2014/31/EU Annex II No. 2 (Conformity assessment for non-automatic weighing instruments)
- EC Directive 2014/34/EU (QS Production of explosion-protected devices according to Annex IV)
- CSA / UL / FM Global (international approvals and corresponding production monitoring)

Continually we verify the compliance to legal requirements, in particular in matters of environment, health and safety. We have also implemented and met further standards imposed by Council Directives and laws, for example, concerning the electrical safety and electromagnetic compatibility, as described in the foregoing. We document our compliance in the form of Declarations of Conformity in the Installation and Operating Instructions for our products.

The certification and accreditation stated above requires that our processes be documented, carried out under controlled conditions, monitored, and continuously improved using suitable measures. We offer extensive qualification programs to our employees. Our quality management system is continuously enhanced and adapted to meet new requirements. Various certifying authorities and auditors confirm this several times each year in their corresponding audits and inspections.

By complying with the standards listed above, we also cover requirements of GMP-Guidelines.

Our products are not classified as medical devices according to the European Medical Devices Directive 93/42/EEC or CFR 21.820.

The following quality-assurance measures and documentation procedures are performed:

Monitoring and Measurement of Processes

Within our processes, various methods for measurement and control are used with respect to customer requirements, process results and process capability:

- Process capability analyses
- Test series
- SPC (Statistical Process Control)
- Statistical methods
- Risk analyses
- Project management
- Preventative maintenance and repair

The person responsible for each process evaluates the results and, provided the results do not conform to the requirements, takes corrective action. Proof of compliance by the methods used, their results, corrective action taken, and their effectiveness is provided in each of our processes.

Monitoring and Measurement of the Product

Throughout the entire development and manufacture of each product, we have integrated quality-assurance process steps. All relevant product features, their conformity with the standards and requirements, and established criteria for product release are inspected and tested, verified where necessary, and documented. If any non-conforming items are discovered, the corresponding procedures for eliminating these are established in the written organizational instructions and standard operating procedures.

Goettingen, April 25th, 2022

Mansoor Mobarak
Sartorius Lab Instruments GmbH & Co. KG
Head of Site Quality

Dr. Andreas Marwitz
Sartorius Corporate Administration GmbH
Manager of Environmental Performance & Reporting