

## Declaration regarding FDA- and GAMP-instruction

FDA-rule 21 CFR Part 11  
“Electronic Records and Electronic Signatures”  
GAMP “Good Automation Manufacturing Practice”  
for **LiquiSonic**-Ultrasonic Measurement systems



### Generals

All departments of SensoTech GmbH ( R&D, production, marketing) are certified according to the requirements of DIN EN ISO 9001.

The development cycles: system design, implementation and system test (validation) are fixed in instructions and are completely comprehensible by an audit administration.

### Data security

The data inside the measurement devices of **LiquiSonic**- devices are monitored by CRC-checksum. As an additional safety feature all configuration data will be stored redundantly.

### Access control

The user administration of the **LiquiSonic**-Controller is implemented by four user levels, each with special access authorization.

Therefore it is guaranteed, that parameters of the devices may be changed by authorized persons only.

### Audit trail

User's performed actions, for example: Logins, changes in products or calibrations will be signed with a timestamp and recorded in a memory by the **LiquiSonic**-Controller. If required, this “log book” can be read out with a module, which is for separate purchase.

### Validation of system

The sensor signal for temperature and ultrasonic velocity are in continuous observation and checked for plausibility.

In case of a defect the error message will indicate in plain text, which signals the superior system an error state.

The ultrasonic probes may be controlled at any time by calibration in pharmaceutical-grade water.

SensoTech GmbH,  
Steinfeldstraße 3,  
D-39179 Magdeburg-Barleben

Tel +49 39203 96 1300  
Fax +49 39203 96 1309  
Internet [www.SensoTech.com](http://www.SensoTech.com)