

## Reference project

# Preparation of an EU Declaration of Conformity for a test station



EXCO is contracted with the testing of the production safety and certificate the EU conformity declaration.

---

### Realization

- Qualification (IQ, OQ, SAT, FAT, validation report, risk analysis)
  - Create a test report of compliance to guidelines of product safety
    - Operation instructions in English compliant to DIN EN ISO 82079-1
    - Risk assessment according to machinery directive 2006/42/EC
    - Risk evaluation
    - Inspection of safety precautions
    - Research of regulations and safety standards
    - Compilation of the complete technical documentation
    - Specification of compliance (RoHS, MRL, NSP, EMC) for supplier parts
    - Review of the technical documentation
    - Issuing of an EU declaration of conformity
-

EXCO combines development expertise with know-how in the area of product safety, qualification and validation.

Stephan Blab, Deputy Head of Division Quality & Compliance, EXCO GmbH

---

### **Clinet benefits**

- Services from one single source from concept to qualification.
  - Efficient risk management by specialists.
- 

### **Client**

Medical technology manufacturer, Ireland

### **Expert contact**



Stephan Blab

T+49 6233 73778-120

[Email contact](#)