

## **Declaration of Compliance to ISO 13485:2016**

Postal address: X-FAB Silicon Foundries SE Transportstraat 1, 3980 Tessenderlo, Belgium

E-mail: info@xfab.com Website: www.xfab.com

X-FAB's quality management system is based on the international quality standard ISO 9001, environmental standard ISO 14001 and automotive quality standard IATF 16949.

The manufacturing sites in Erfurt, Corbeil and Dresden have introduced successfully the energy management system according ISO 50001.

This combined quality management system is supervised by a certification body on regular intervals and the maturity of this system is confirmed by customer audits as well.

As the medical market is one of X-FAB's strategic markets, it is X-FAB's goal to support our customers by meeting the main medical standards ISO 13485.

This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

Internal assessments confirmed that the installed Quality Management System at X-FAB covered all requirements of the ISO 13485 standard except the product and application related assurance activities and requirements. As X-FAB is a technology foundry and sells processed silicon wafers to customers, the responsibility of the final product remains on the customer side.

Due to above mentioned reason it is not appropriate to get an ISO 13485 certification however X-FAB is committed to support its customers towards fulfilling the ISO 13485 quality standard. Special requirements from customer towards X-FAB as Foundry are documented in a separate supplier agreement as reference for collaboration and audit purposes.

Erfurt, July 24, 2018

Frank Lorenz VP Quality

Rudi De Winter

CEO