ArminLabs GmbH
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To whom it may concern

I would like to take this opportunity to confirm that the tests provided by ArminLabs for Lyme Disease and various co-infections are compliant and conform to the various stringent EEC and German standards for in vitro diagnostic tests and meet the standards applied to medical devices and more, as stated in the following;

CE - Declaration of conformity

Since 1998 AID's QM (Quality Management) complies with the European Law on Medical Devices (Medizinproduktegesetz), particularly with the in vitro diagnostic directive (IVDD) 98/79/EC. IVDD covers the placing on the market and putting into service of in vitro diagnostic medical devices. AID GmbH developed and manufactured products meet all of the relevant essential requirements contained within the IVDD. AID GmbH products carrying the CE sign can be sold without further validation anywhere in the European Union.

DIN EN ISO 13485:2012 + AC:2012

ISO 13485 is a quality system standard designed specifically for medical device companies. The ISO 13485 standard supplements ISO 9001 and has many of the same requirements. However, there are additional requirements for process control, design control, retention of records, accountability, traceability and more. AID GmbH is certified according to DIN EN ISO 13485.

GMP/ GLP

GMP is as a quality standard included in the German Law on Pharmaceutical Products (Arzneimittelgesetz). AID GmbH products (AID Reader Systems) are designed to work in a GMP/ GLP environment according to GMP conditions. They can be adapted to individual customer wishes at any time to meet the requirements of the severe internal and external guidelines (GMP/ GLP).

DIN EN ISO 9001:2008-12

ISO 9001 is a standard for quality management systems. It is designed to help organizations ensure that they meet customers' needs. AID GmbH is certified according to DIN EN ISO 9001.

21CFR Part 11

Part 11 of the Code of Federal Regulations defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records. The software of all AID devices can be adjusted to meet these requirements.

Yours sincerely

Armin Schwarzbach MD PhD

Specialist for laboratory medicine