EC Declaration of Conformity

In accordance with EN ISO/IEC 17050-2004

We, Axlab Innovation ApS, Bygstubben 4, 2950 Vedbæk, Denmark as Legal Manufacturer declare that:

Product: BiopSafe ®, container with lid (containing liquid)

Is manufactured at SP Medical A/S, Møllevej 1, 4653 Karise, Denmark

In accordance with the following Directives:

98/79 EEC Conforms with the essential requirements of the

In Vitro Diagnostics Directive and it's amending Directives.

Classification: General IVD Medical Device.

Conformity Assessment route: Annex III applied

In addition, the following internally used standard applies:

ISO 13485:2012 Quality Management System requirements.

I hereby declare that the equipment named above has been tested and found to comply with the relevant section of the above referenced specifications. The unit complies with all essential requirements of the Directives.

Date: 27 JANUAR 2017

Signed:

CEO Ole Jakobsen