Axlab Innovation

EC Declaration of Conformity

In accordance with EN ISO/IEC 17050—1:2014

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

Product: BiopSafe ®, Container and lid (containing liquid)

Is manufactured at SP Medical A/S, Møllevej 1, DK-4653 Karise, in accordance with the following Directives:

98/79/EC Conforms to the essential requirements of the In Vitro Diagnostics Directive and its amending directives.

Classifications: 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 sections of the above referenced specifications. The unit complies with all essential requirements of the Directives.

CEO Ole Jakobsen

Date: 13 December 2016

AXLAB INNOVATION APS
BYGSTUBBEN 4
DK-2950 VEDBÆK
TEL. +45 29 39 30 10
MAIL@BIOPSAFE.COM
WWW.BIOPSAFE.COM