



CE - Declaration of Conformity

Manufacturer: möLab GmbH
Dietrich-Bonhoeffer-Straße 9
D-40764 Langenfeld

Product Name: mö-screen Neutralizing Antibody Test

Model: Cassette

Catalog-No.: 0240007

Classification: Non listet devices of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards.
All supporting documentations are retained under the premises of the manufacturer.

General applicable directives: Directive 98/79/EC Of the European Parliament an of the council of 27 October 1998 on in-vitro Diagnostika

Standard applied: EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002, EN ISO 17511:2003, EN ISO 15193:2009, EN ISO 15194:2009, EN 13641:2002, EN ISO 15223-1:2012, EN ISO 23640:2015, EC 1272/2008

Expiration Date: 30.01.2026

Place/ Date of Issue: Langenfeld, 01.02.2021

A handwritten signature in black ink, appearing to read 'M. Schürmann', is written over a horizontal line.

Mathias Schürmann
General Manager