Bios GmbH Labordiagnostik Beratung und Vertrieb ◆ Postfach 70 03 32 ◆ D – 81303 München

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Declaration of Conformity*

for vitro diagnostics

with In-vitro-Diagnostic Device Directive (IVDD) 98/79/EC, Annex III

Bios GmbH Labordiagnostik Beratung und Vertrieb
Hofmannstr. 7, D-81379 München
Deutschland

certifies in **own responsibility** that the products listed in attachment comply with all Essential Requirements (Annex III) oft the IVDD (Directive 98/79/EC).

This declaration of Conformity is signed below, certifying these requirements have been met and documented.

München im Juli 2015

U. König

Dr. Ursula König
Head of production and Regulatory Affairs

Dr. Elfriede Schulz
President

Attachment:
List Autoantibodies Assays
List Antibodies to Bacteria
List Antibodies to Fungi, Parasites, Protozoa
List Antibodies to Viruses

*** As of 26. May 2022, IVDR (EU) 2017/746 replaces IVDD 98/79/EC.**

According to article 110 – transitional regulations – paragraph 4 of the IVDR (EU) 2017&746, products legitimately put on the market in accordance with directive 98/79/EC before **26. May 2022** may still be provided or launched in the market until **27. May 2025**

München, July 2022

U. König

Dr. Ursula König
Head of production and Regulatory Affairs

Dr. Elfriede Schulz
President