ESTABLISHED INNOVATIONS IN DIAGNOSTICS

DECLARATION OF CONFORMITY

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We declare under our sole responsibility that the products listed below are in compliance with the essential requirements of the "Directive 98/79/EC of the European parliament and of the council of 27 October 1998 on *in vitro* diagnostic medical devices (IVDD). According to the IVDD the products are classified as "Other IVD" (all devices other than those covered by Annex II and self-testing devices). Conformity assessment was performed according to Annex III.
In addition, all products are in accordance with the requirements on post-market surveillance, vigilance and market surveillance of the Regulation (EU) 2017/746 of the European parliament and of the council of 5 April 2017 on in vitro diagnostic devices (IVDR).

All products are marked with the CE - symbol.

Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
CS-012	StripAssay® Detection Reagents	1.5 ml DNAT, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
CS-017	StripAssay® Detection Reagents 48	1.5 ml DNAT, 65 ml Hybridization Buffer, 200 ml Wash Solution A, 65 ml Conjugate Solution, 200 ml Wash Solution B, 65 ml Color Developer	48 tests	Other IVD	Annex III IVDD

Vienna, May 25th, 2022

Martin Zeppetzauer, MRes
Chief Executive Officer
ViennaLab Diagnostics GmbH