EU Declaration of conformity

according to the European In-Vitro-Diagnostics
Regulation (EU) 2017/746 and appendix IV

We,

Waldeck GmbH & Co. KG
Havixbecker Straße 62
48161 Münster

Germany

Single registration number (SRN):	DE-MF-000029874
Basis-UDI-DI:	42511373TestsimpletsKD
EMDN Code:	W0103010301

hereby declare under our sole responsibility in our role as manufacturer that the devices listed in Appendix 1 comply with the conformity assessment procedure for Class A IVDs referred to in Article 48 (10).

All applicable essential safety and performance requirements of Annex I have been met and technical documentation has been prepared in accordance with Annexes II and III of the same Regulation.

The classification of the products listed above was carried out in accordance with Annex VIII of the above-mentioned Regulation. Classification rule 5 a) was determined to be applicable.

We declare that the product covered by this declaration is in conformity with Regulation (EU) 2017/746 and, where applicable, other relevant Union legislation providing for the drawing up of an EU declaration of conformity

This declaration is valid for products placed on the market from the date of issue.

This document is valid until 31.12.2025.

06.10.2023, Münster

i.A. Wolfgang Schrader

Dr. W. Schräder
(legally binding signature)

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Anlage 1:

Product name	Description	Item number	GTIN (UDI-DI)
Testsimplets®	Sales package, Content 50 pieces	191574	4251137321735
Testsimplets®	Sample package, Content 10 pieces	191574.10	4251137330676