Declaration of Conformity

Trade name:	Trinity Biotech		
Manufacturer:	Trinity Biotech USA 2823 Girts Road Jamestown, NY, USA 14701 Tel: + 716 483 3851 Fax: + 716 488 1990	Authorized Representative:	Trinity Biotech, plc. IDA Business Park Bray, Co. Wicklow, Ireland Tel: + 353 1 276 9800 Fax: + 353 1 276 9888

This Declaration of Conformity is issued under the sole responsibility of the manufacturer, Trinity Biotech USA.

Basic UDI-DI:	05391516744829 / 05391516744836
GMDN Code:	51804
GMDN Term:	Treponema pallidum immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
Product Name:	**Captia™ Syphilis (T. pallidum) IgG**
Catalogue Number:	**800-970 / 800-960**
Intended Purpose:	Captia™ Syphilis (*T. pallidum*) IgG is an enzyme immunoassay for the qualitative detection of IgG antibodies to *T. pallidum* in serum specimens, to be used in conjunction with non-treponemal testing to provide serological evidence of infection with T. pallidum (the agent of syphilis). Captia™ Syphilis (*T. pallidum*) IgG is also intended for testing of serum or plasma specimens to screen blood and/or plasma donors to exclude a history of syphilis.
Conformity Assessment Route:	Annex III for a non-self-testing kit

The device covered by this declaration is in conformity with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

References to common specifications:	Not applicable
Name and identification number of the Notified Body:	N/A
Assessment Procedure(s) utilized to verify conformity:	ISO13485:2016 / EN ISO 13485:2016 MDSAP (Medical Device Single Audit Program) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices including all applicable standards
Certificates Issued:	ISO 13485:2016/ EN ISO 13485:2016; Certificate 1780.181030, Issued October 30, 2018 ISO 13485:2016/ MDSAP; Certificate 1781.181030, Issued October 30, 2018 EC Certificate; Certificate N/A, Issued N/A

Issuance of Declaration:

Trinity Biotech agrees to develop, implement, and maintain a documented post-production monitoring process, notification of reportable events under the European Medical Device Vigilance System Guidelines.

Place:	Trinity Biotech USA		
Name:	Pamela Netzel	Signature:	P S Netzel
Title:	Director of Quality Systems		
Date:	September 28, 2020 Digitally signed by Bolea Petru Date: 2021.09.27 14:29:00 EEST Reason: MoldSign Signature Location: Moldova		