EC Declaration of Conformity (Directive 98/79EC)

Manufacturer:	Griff IVD Ltd 2 Victoria Hall, Coombe Lane, Axminster Devon, EX13 5AX, United Kingdom.
Manufacturer Identification Code:	0000010084
Competent Authority:	Medicines and Healthcare Product Regulatory Agency (MHRA) Competent Authority GB/CA01
Product Details:	See EC Declaration of Conformity List (Attached)
Classification:	General IVD (Others)
Conformity Assessment Route:	Annex III IVDD

We hereby declare that the devices named in the EC Declaration of Conformity List (See Attached) comply with the requirements of DIRECTIVE 98/79EC, on in vitro diagnostic medical devices.

Standards Applied:	EN ISO 13485:2016	EN ISO 9001:2015
	EN ISO 14971:2012	EN ISO 18113-2.2011
	EN ISO 15223-1.2016	EN ISO 13612:2002
	EN ISO 23640:2015	EN ISO 13641:2002

Signed:

Name:	Phil Winton
Position:	Director
Place:	Griff IVD Ltd, 2 Victoria Hall, Coombe Lane, Axminster, Devon, EX13 5AX, United Kingdom.
Date:	12th November 2020

Company Registration No: 12450675. Registered Office: 2 Victoria Hall, Coombe Lane, Axminster, Devon EX13 5AX. United Kingdom.
VAT No. 357953257

EC Declaration of Conformity List

GMDN Classification	Description	Product Code
63271	Beta-Haemolytic multiple group streptococcus streptolysin O antibody IVD, kit, agglutination rapid	LS/ASO50T LS/ASO100T
63234	C-Reactive Protein (CRP) IVD, kit, agglutination rapid.	LS/CRP50T LS/CRP100T
55112	Rheumatoid Factor IVD, kit, agglutination	LS/RA50T LS/RA100T
51659	Staphylococcus aureus culture isolate antigen IVD, kit, agglutination	STA/50T STA/100T
51701	Multiple Streptococcus bacterial species culture isolate identification IVD, kit	STP/650TA STP/650TE
51819	Treponema Pallidum reagin antibody IVD, kit, agglutination	RPR/100T RPR/500T VDRL/005 VDRL/010
61225	Treponema Pallidum immunoglobulin G (IgG) /IgM antibody IVD, kit, agglutination	TPHA/100T TPHA/200T TPHA/1000T
63240	Multiple febrile infection associated bacteria antibody IVD, kit, agglutination	SA/TH5 SA/TO5 SA/AH5 SA/AO5 SA/BH5 SA/BO5 SA/CH5 SA/CO5 PA/OX2.5 PA/OX19.5 PA/OXK.5 BA/AB5 BA/MEL5 SA/008C SA/008

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