



DECLARATION OF CONFORMITY

No: BP 0006

Manufacturer: Trinity Biotech Plc.
Address: IDA Business Park,
Southern Cross Road,
Bray, Co. Wicklow,
Ireland.
Product Biopool Protein S Normal Control Plasma
Product Code: 40225

The product described above is in conformity with:

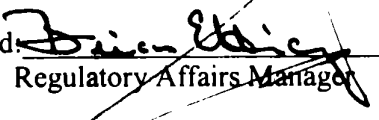
Document No.	Title	Edition
98/79/EC	IVD Directive as implemented into Irish Law under SI304:2001	1998
EN ISO 9001	Quality Systems	1994
IS EN 46001	Quality Systems	1996
ISO 13485	Quality Systems	1996
ISO 14971	Risk Management	2000
IS EN 375	IVD Systems – requirements for labelling	1993
ISO11014-1	Safety data sheet for chemical products	1994
IS EN 45014	General criteria for supplier's declaration of conformity	1989
IS EN 13640	Stability testing of <i>in vitro</i> diagnostic reagents	2002

Additional Information:


Classification: Non-Listed in Annex II of IVD Directive 98/79/EC

EDMA Code: 13 02 50 01 00

Place and Date of Issue: Trinity Biotech Plc, Ireland.

Signed: 
Regulatory Affairs Manager

Date: 5 Nov 03

Signed: 
President of Trinity Biotech.

Date: 11 Nov 03