

DECLARATION OF CONFORMITY

No: BP0027

Manufacturer: Trinity Biotech Plc.

Address: IDA Business Park,
Southern Cross Road,
Bray, Co. Wicklow,
Ireland.

**Product and
Product Codes:** Biopool Bioclot Protein C 40133
Protein C Control Plasma 40112


The product described above is in conformity with:

Document No.	Title	Edition
98/79/EC	IVD Directive as implemented into Irish Law under S1304:2001	1998
EN ISO 9001	Quality Systems	2000
IS EN 46001	Quality Systems	1997
ISO 13485	Quality Systems	1996
ISO 14971	Risk Management	2000
IS EN 375	IVD Systems – requirements for Labeling	2001
ISO 11014-1	Safety data sheet for chemical Products	1994
IS EN 45014	General criteria for supplier's Declaration of conformity	1989

Additional Information:

Classification: Non-Listed in Annex II of IVD Directive 98/79/EC.
EDMA Code: 13 02 06 08 00

Place and Date of Issue: Trinity Biotech Plc., Ireland. 02 October 2003.

Signed: 
PP Regulatory Affairs Manager

Date: 11 Nov 03

Signed: 
President of Trinity Biotech Plc

Date: 21. 11. 03