Dia.Pro
Diagnostic
BioProbes srl

DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA COLUMELLA N° 31 - MILANO - ITALY
EUROPEAN REPRESENTATIVE	NONE
PRODUCT	HDV IgM – CODE DIM.CE
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.
ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED	ISO 9001:2000/ISO 13485:2000 //EN 1441:1997 // EN ISO 14971:2000 // EN 375:2001 // ISO 15223:2000 // EN 980:1996+A1:1999+A2:2001 // EN 13612 :2002 // EN 13640 :2002 // EN 12286 :1998+A1 :2000 // EN 12287 :1999 // DL 172/2001 // IT. LAW N° 626/94
NOTIFIED BODY	MINISTRY OF HEALTH – SPAIN – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM(in accordance with Annex IV(except Section IV) of the Directive 98/79/EC), N° 2003 12 0388 CT, RELEASED BY EC NOTIFIED BODY N° 0318 • DESIGN CERTIFICATE N° 2003 12 0395 RELEASED BY EC NOTIFIED BODY N° 0318 • EN-ISO 13485:2000 N°2003 12 2388 EN
START OF CE-MARKING	JANUARY 2004

PLACE & DATE OF ISSUE	MILANO – 01/2004
SIGNATURE **Legal Representative**