



Dia.Pro
Diagnostic
Bio**Probes**

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HDV Ab CODE: DAB.CE (96 tests)
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.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none">• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318• DESIGN CERTIFICATE N° 2003 12 0393 ED RELEASED BY EC NOTIFIED BODY N° 0318• UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.

Rev: 05/2018