



Dia.Pro  
**Diagnostic**  
Bio**Probes**

# EC DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
<b>PRODUCT</b>	<b>HBs Ab</b> CODE: <b>SAB.CE</b> (96 tests)
<b>CLASSIFICATION</b>	ANNEX II – LIST A
<b>CONFORMITY ASSESSMENT ROUTE</b>	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.**

<b>NOTIFIED BODY</b>	AEMPS – n° 0318
<b>(EC) CERTIFICATE(S)</b>	<ul style="list-style-type: none"><li>• 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</li><li>• DESIGN CERTIFICATE N° 2003 12 0390 ED RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318</li></ul>

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

Rev: 05/2018