



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	HBc Ab CODE: BCAB.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 0391 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) – MARCH 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 0318



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MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HCV Ab CODES: CVAB.CE (192 tests) CVAB.CE.96 (96 tests) CVAB.CE.480 (480 tests) CVAB.CE.960 (960 tests) CVAB.CE.DB (192 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

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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 0392 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) – MARCH 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	

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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



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EC DECLARATION OF CONFORMITY

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

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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 0390 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



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MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HBs Ag one Version ULTRA CODES: SAG1ULTRA.CE (192 tests) SAG1ULTRA.CE.96 (96 tests) SAG1ULTRA.CE.480 (480 tests) SAG1ULTRA.CE.960 (960 tests) SAG1ULTRA.CE.DB (192 tests)
CLASSIFICATION	ANNEX II – LIST A
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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° 0318DESIGN CERTIFICATE N° 2008 12 0588 ED RELEASED BY EC NOTIFIED BODY N° 0318UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – DECEMBER 2008
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MARCH 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 03/2018