Dia.Pro
Diagnostic
BioProbes

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 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
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)	• 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° 2008 12 0588 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 – DECEMBER 2008
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MARCH 2018
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA.PRO DIAGNOSTIC BIOPROBES srl

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