Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. 2P150428.HABUS27

Certificate's Holder:	Hangzhou Alltest Biotech Co., Ltd. 550#, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou-310018, P. R. China.
Certification ECM Mark:	ENTE CERTIFICAZIONE MACCHINE – European Conformity – SAFETY COMPLIANCE MARK – ® – Type Approved
Product:	In Vitro Diagnostic Kit – Oncology Tests – Professional Use
Types:	CEA Rapid Test (Whole Blood / Serum / Plasma), AFP Rapid Test (Whole Blood / Serum / Plasma), FOB Rapid Test (Feces)
Verification to:	Standard: EN ISO 13485:2012/AC:2012, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 15193:2009, EN ISO 15194:2009, EN 13640:2002, EN 13641:2002, EN 1041:2008, ISO 15223-1:2012 related to CE Directive(s): 98/79/EC (In Vitro Diagnostic Medical Devices)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Certification Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. Regulation can be found at www.entecerma.it.
Whereas the Manufacturer is responsible of the CE certification of the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market.
The Manufacturer is also responsible to maintain efficient the internal production control to ensure the product(s) are in compliance with the Certification ECM Mark.
This certificate can be checked for validity at www.entecerma.it

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Chief Manager
Tim Mahan

Expiry date 27 April 2020

Deputy Manager
Viola Miller

Digitally signed by Varman Irina
Date: 2020.04.07 16:44:40 EEST
Reason: MoldSign Signature
Location: Moldova

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