

DECLARATION OF NOTIFICATION

according to Article 10 of the In Vitro Diagnostic Medical Device Directive 98/79/EC

DECLARATION N°: 107/33

MANUFACTURER:

**Immunostics, Inc.
3505 Sunset Ave./1750 Brielle Ave., Suite A5
Ocean, NJ 07712 USA**

Device designation :

Listed in the attached annex

MediMark® Europe Sarl, European Authorized Representative of **Immunostics, Inc. 3505 Sunset Ave. Ocean, NJ 07712, USA**, hereby declares that for the above mentioned product categories, the notification according to Article 10 of 98/79EC Directive has been performed on **2012-02-15** with the necessary information to the French Competent Authority which is in charge of the registration into the European Databank(*).

Consequently, the above mentioned devices bearing the CE Mark can be shipped into the European Economic Area and put into service in the EU Member States where the national provisions concerning languages on the labels and instructions for use are met.

MediMark® Europe Sarl keeps and makes available to the national authorities for inspection purpose the EC declarations of conformity issued by the Manufacturer and the technical documentations referred to in the Directive 98/79/EC Annexes relevant to the above mentioned device categories.

Date: **2012-02-15**Philippe Léglise
Co-Chairman

(*)An Acknowledgement of receipt may be issued later by the French Competent Authority. A scan of that document will be communicated to the relevant Manufacturer upon receipt at MediMark® Europe.

ANNEX TO DECLARATION N°: N°: 107/33**MANUFACTURER:**

Immunostics, Inc.
3505 Sunset Ave./1750 Brielle Ave., Suite A5
Ocean, NJ 07712 USA

Product designation :

- **hema-screen SPECIFIC** (Cat N°: HSSP-25);
- **ASO COLOR ENHANCED** (Cat N°: ASOCE-25, ASOCE-50, ASOCE-100);
- **IMMUNOLEX/ASO** (Cat N°: ASO-25, ASO-50, ASO-100);
- **IMMUNO/C-REACTACOL*** (Cat N°: CRC-50, CRC-100);
- **IMMUNO/CRP*** (CRPA Latex) (Cat N°: CRP-50, CRP-100);
- **IMMUNO/HEMA SCREEN*** (Cat N°: HS-50, HS-100);
- **HEMA SCREEN STAT** (Cat N°: HSTAT-50);
- **IMMUNO/HEMA SCREEN*** (DEVELOPER) (Cat N°: HSDV-8);
- **IMMUNO/HEMA SCREEN*** PATIENT PAK (Cat N°: HSPP-50);
- **IMMUNO/LEX-IM*** (IM LATEX) (Cat N°: IMLX-25, IMLX-50, IMLX-100);
- **IMMUNO/COLOR IM*** (COLOR IM) (Cat N°: IMC-25, IMC-50, IMC-100);
- **IMMUNO/IM MONOCOL*** (MONOCOL) (Cat N°: IMM-25, IMM-50, IMM-100);
- **MONOCOL/LEX*** (MONOCOL/LEX) (Cat N°: MCLX-25, MCLX-50, MCLX-100);
- **IMMUNO/RHEUMACOL*** (RHEUMACOL) (Cat N°: RH-25, RH-50, RH-100) (Rheumatoid Factor);
- **IMMUNO/LEX-RA*** (RA/RF Undiluted) (Cat N°: RA-50U, RA-100U) (Rheumatoid Factor);
- **IMMUNO/RA*** (RA/RF LATEX) (Cat N°: RA-50, RA-100) (Rheumatoid Factor);
- **IMMUNO/RHEUMACOL-LEX*** (RHEUMACOL-LEX) (Cat N°: RHLX-50 RHLX-100) (Rheumatoid Factor);
- **IMMUNO RPR** (RPR) (Cat N°: RPR-100 [NC, 2C, 3C], RPR-500 [NC, 2C, 3C]);

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3505 Sunset Ave./1750 Brielle Ave., Suite A5
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Product designation (Cntd):

- **IMMUNO/STREP A DETECTOR (DIPSTICK)** (Cat N° : IDSTREP-25);
- **STAPHACOL** (Cat N°: STP-50, STP-100);
- **IMMUNO/LEX SLE (SLE)** (Cat N°: SLE-25, SLE-50, SLE-100) (Systemic Lupus Erythematosus);
- **IMMUNO/hCG DETECTOR STIX (DETECTOR STIX)** (Cat N°: IHS-25, IHS-50, IHS-100);
- **IMMUNO/hCG DETECTOR COMBI (DETECTOR COMBI)** (Cat N°: IDC-25, IDC-50,-IDC-100);
- **IMMUNO/CEPT-D* (hCG POLYCLONAL INDIRECT)** (Cat N°: 4350, 4350-D, 43100, 43100-D);
- **IMMUNO/CEPT-D* DIRECT (hCG DIRECT)** (Cat N°: MD-50, MD-100);
- **IMMUNO/CEPT-D* (hCG MONOCLONAL INDIRECT)** (Cat N°: MPD-50(D), MPD-100(D));
- **IMMUNO/PREGNACOL 2000 (PREGNACOL 2000)** (Cat N°: PRC2000-50, PRC2000-100, PCR2000-1000);
- **IMMUNO/PREGNACOL (PREGNACOL)** (Cat N°: PRC-50, PRC-100);
- **IMMUNO/hCG DETECTOR "PREMIER" (CASSETTE)** (Cat N°: IHD/P-25, IHD/P-50, IHD/P-100);
- **IMMUNO/ROSE-B BRUCELLA SLIDE TEST** (Cat N°: RB-100);
- **FEBRILES/BACTACOL ANTIGENS/CONTROLS (FEBRILES)** (Cat N°: FA-00 to 0016, FA-025, FC-007 & 008);
- **FEBRILES/BACTACOL TEST KIT (FEBRILE TEST KIT)** (Cat N°: FK-600 [NC, 2C]);
- **WIDAL TEST KIT (WIDAL TEST KIT)** (Cat N°: WTK-400 [NC, 2C], WK-800 [NC, 2C])

Date: **2012-02-15**Philippe Légli
Co-Chairman

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