



your mail from
your references

our references: IVD004-05
date : 17/01/2005

Mr. M. Ohn

**Obelis S.A.
Av. De Tervueren, 34 Bte 44
B-1040 Bruxelles**

Dear Mr. Ohn,

Please find enclosed the original notification form for the CE marked in vitro diagnostic medical devices, notified to the Belgian Competent Authority. This notification form is an acknowledgement of your declaration that the in vitro diagnostic medical devices, mentioned hereunder, fully comply with the Directive 98/78 of the European Parliament and of the Council. Be aware that it is an offence to place on the market non-complying devices bearing the CE marking. This form does not represent an accreditation or approval by the Belgian Competent Authority.

Please inform us of any changes (change of company information, change of address, significant change of product, change of certificate) and of the discontinuation of the product.

In accordance with the dispositions of the directive 98/79, you have the obligation to send a copy of your notification request to the Competent Authorities of the other EU member states, as long as the European database does not exist. The electronic formats of the notification forms, completed with the registration number, were sent to you. An updated list of the Competent Authorities is available on our website: <http://www.iph.fgov.be/ClinBiol/IVDfile/Notification.pdf>.

Sincerely yours.

Dr. A. Van Nerom
IVD Competent Authority

Dr. J.C. Libeer
Department Head





our references: IVD004-05
date : 17/01/2005

Re: notification of IVD products according to the directive 98/79

Competent Authority: BE/CA02

Manufacturer: Pointe Scientific, Inc., 5449 Research Drive, Canton MI 48188, USA

Authorized representative: OBELIS S.A., Av. de Tervuren 34 Bte 44, B-1040, Brussels, Belgium

Date of registration: 17/01/2005

Type of IVD: reagents for professional use

IVD	EDMS code	Registration number
AST (ref HA761, A7561, A7560)	11 01 01 1000	BE-CA02-212-03
Auto LDL	11 01 01 2100	BE-CA02-213-03
Auto HDL	11 02 07 1500	BE-CA02-214-03
Auto HDL/LDL Calibrator	11 50 03 0100	BE-CA02-215-03
β -hydroxybutyrate	11 02 01 9000	BE-CA02-216-03
β -hydroxybutyrate Controls	11 50 02 9000	BE-CA02-217-03
Bilirubin Calibrator	11 50 03 0200	BE-CA02-218-03
BUN (ref B7550, B7551, HB752, B7552)	11 02 01 0400	BE-CA02-219-03
Bun Standard	11 50 03 0300	BE-CA02-220-03
Calcium (ref C7508, C7529, HC902, C7503)	11 03 01 0300	BE-CA02-221-03
Calcium Standard	11 50 03 0300	BE-CA02-222-03
Chemistry calibrator	11 50 03 0100	BE-CA02-223-03
Chemistry Control Level I, II	11 50 01 0200	BE-CA02-224-03
Chloride	11 03 01 0400	BE-CA02-225-03
Chloride Standard	11 50 03 0300	BE-CA02-226-03
Cholesterol (ref HC710, C7509, C7510)	11 02 01 0500	BE-CA02-227-03
Cholesterol Calibrator	11 50 03 0200	BE-CA02-228-03
Cholesterol Standard	11 50 03 0300	BE-CA02-229-03
Cholesterol-HDL Standard	11 50 03 0300	BE-CA02-230-03
CK (ref C7512, HC722, C7522)	11 01 01 1300	BE-CA02-231-03
CK-MB	11 01 01 1400	BE-CA02-232-03
CK-MB Control Set	11 50 02 9000	BE-CA02-233-03
CO2	11 03 01 0200	BE-CA02-234-03
CO2 Standard	11 50 03 0300	BE-CA02-235-03
Cortisol	12 06 02 0400	BE-CA02-236-03
Creatinine (ref C7539, HC739)	11 02 01 0700	BE-CA02-237-03

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Type of IVD: reagents for professional use: continued

CRP HS	12 11 01 0900	BE-CA02-238-03
CRP Calibrator set	11 50 03 0200	BE-CA02-239-03
CRP Control set	11 50 02 9000	BE-CA02-240-03
Direct Bilirubin (ref B7538, HB936)	11 02 01 0300	BE-CA02-241-03
Estradiol	12 05 01 0300	BE-CA02-242-03
Free Thyroxine	12 04 01 0200	BE-CA02-244-03
Free Triiodothyronine	12 04 01 0100	BE-CA02-245-03
Fructosamine	11 02 01 1000	BE-CA02-246-03
Fructosamine control set	11 50 02 9000	BE-CA02-247-03
FSH	12 05 01 0400	BE-CA02-248-03
G6PD	11 01 01 9000	BE-CA02-249-03
GGT (ref G7570, HG959, G7571)	11 01 01 1600	BE-CA02-250-03
Glucose (ref G7518, HG920, G7517, G7519, G7521)	11 02 01 1300	BE-CA02-251-03
Glucose Standard	11 50 03 0300	BE-CA02-252-03
Glycohemoglobin	11 02 01 1400	BE-CA02-253-03
Glycohemoglobin A1c	12 06 01 0600	BE-CA02-254-03
Glycohemoglobin Control Set	11 50 02 9000	BE-CA02-255-03
Glycohemoglobin Standard	11 50 03 0200	BE-CA02-256-03
HBDH	11 01 01 1800	BE-CA02-257-03
HCG	12 05 02 0500	BE-CA02-258-03
HDL Cholesterol Precipitating Reagent Set	11 02 07 1500	BE-CA02-259-03
HDL	11 50 03 0300	BE-CA02-260-03
Hemoglobin	13 01 02 0100	BE-CA02-261-03
Hemoglobin Standard	11 50 03 0200	BE-CA02-262-03
Hemoglobin Control Set	11 50 02 9000	BE-CA02-263-03
IgE	12 02 01 0200	BE-CA02-264-03
Iron/TIBC	11 02 01 1600	BE-CA02-265-03
Iron	11 02 01 1600	BE-CA02-266-03
Iron Standard	11 50 03 0300	BE-CA02-267-03
Lactate	11 02 01 1800	BE-CA02-268-03
Lactate Standard	11 50 03 0300	BE-CA02-269-03
LDH (ref HL956, L7535, L7572)	11 01 01 2000	BE-CA02-270-03
LH	12 05 01 0500	BE-CA02-271-03
Lipase	11 01 01 2300	BE-CA02-272-03
Lipase Standard	11 50 03 0200	BE-CA02-273-03
Lipid Control Set	11 50 02 0200	BE-CA02-274-03
Lipoprotein (a)	12 01 04 9000	BE-CA02-275-03
Magnesium Standard	11 50 03 0300	BE-CA02-276-03
Magnesium (ref M7527, HM929)	11 03 01 0700	BE-CA02-277-03
Microalbumin	11 02 01 0100	BE-CA02-278-03
Microalbumin Calibrator Set	11 50 03 0200	BE-CA02-279-03
Microalbumin Control Set	11 50 90 0200	BE-CA02-280-03
Microprotein	11 02 01 3000	BE-CA02-281-03
Microprotein Standard	11 50 03 0300	BE-CA02-282-03
Phosphorus (ref P7516, HP916)	11 03 01 0800	BE-CA02-283-03
Phosphorus Standard	11 50 03 0300	BE-CA02-284-03
Potassium	11 03 01 0900	BE-CA02-285-03
Potassium Calibrator	11 50 03 0200	BE-CA02-286-03
Progesterone	12 05 01 0600	BE-CA02-287-03
Prolactin	12 05 01 0800	BE-CA02-288-03
RF	12 11 01 1000	BE-CA02-290-03
RF Calibrator Set	11 50 03 0200	BE-CA02-291-03
Sodium	11 03 01 1000	BE-CA02-292-03
Total Bilirubin (ref B7576, HB979)	11 02 01 0300	BE-CA02-293-03
Testosterone	12 05 01 1000	BE-CA02-294-03

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Type of IVD: reagents for professional use: continued

Thyroid Stimulating Hormone	12 04 01 1100	BE-CA02-295-03
Total Protein (ref T7528, HT928)	11 02 01 3000	BE-CA02-296-03
Total Protein Standard	11 50 03 0300	BE-CA02-297-03
Total Thyroxine	12 04 01 0700	BE-CA02-298-03
Triglyceride (ref T7531, HT732, T7532)	11 02 01 3100	BE-CA02-299-03
Triglyceride Standard	11 50 03 0300	BE-CA02-300-03
Triiodothyronine	12 04 01 0500	BE-CA02-301-03
Ultra Sensitive Thyroid Stimulating Hormone	12 04 01 9000	BE-CA02-302-03
Uric Acid (ref U7580, HU982, U7581)	11 02 01 3200	BE-CA02-303-03
Uric Acid Standard	11 50 03 0300	BE-CA02-304-03
Microprotein Control Set	11 50 90 9000	BE-CA02-305-03
Apolipoprotein b	12 01 04 0300	BE-CA02-306-03
Apolipoprotein a calibrators	12 50 01 80 00	BE-CA02-307-03
Apolipoprotein A1	12 01 04 0100	BE-CA02-308-03
Amylase (HA965, A7564)	11 01 01 0700	BE-CA02-309-03
Alcohol/Ammonia Control	12 50 90 9000	BE-CA02-310-03
ASO Assay	12 11 01 0400	BE-CA02-311-03
ASO multicalibrator set	12 50 01 8000	BE-CA02-312-03
Ammonia standard 500, 100)	11 50 03 0300	BE-CA02-313-03
Ammonia	11 03 01 0100	BE-CA02-314-03
ALT (ref A7526, HA726, A7525)	11 01 01 0300	BE-CA02-315-03
Alkaline Phosphatase (ref A7516, HA716, A7505)	11 01 01 0500	BE-CA02-316-03
Alcohol Standard	11 50 03 0300	BE-CA02-317-03
Alcohol	11 02 01 90 00	BE-CA02-318-03
Albumin (ref HA901, A7502)	11 02 01 0100	BE-CA02-319-03
Albumin Standard	11 50 03 0300	BE-CA02-320-03
Apolipoprotein a (Lpa)	12 01 04 2100	BE-CA02-321-03
Apolipoprotein B Calibrators	11 50 03 0200	BE-CA02-322-03
Creatinine standard	11 50 03 0300	BE-CA02-482-03
Acid Phosphatase	11 01 01 02 00	BE-CA02-483-03
ISE standard 1 solution	11 04 04	BE-CA02-723-04
ISE Standard High	11 04 04	BE-CA02-724-04
ISE Standard 2	11 04 04	BE-CA02-725-04
ISE Standard Low	11 04 04	BE-CA02-726-04
Random Access Solution	11 04 04	BE-CA02-727-04
ISE Reference Solution	11 04 04	BE-CA02-728-04
Cell Wash	11 04 04	BE-CA02-729-04
Precision Test Dye	11 04 04	BE-CA02-730-04
Pointe 180 II spectrophotometer	GMDN 36411	BE-CA02-004-05
Pointe 180 PLUS spectrophotometer	GMDN 36411	BE-CA02-005-05
Stat Fax 3200 microtiter plate spectrophotometer	GMDN 36411	BE-CA02-006-05
Pointe 180 SR microstrip reader	GMDN 36411	BE-CA02-007-05



Dr. A. Van Nerom
IVD Competent Authority



Dr. J.C. Libeer
Department Head

This notification contains 3 pages and replaces the certificate issued 15-09-2004

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Federal Public Service
Health, Food Chain Security
and Environment



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