

Azienda	DIAMETRA srl	Mod. DDC000-1
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The undersigned Dia.Metra s.r.l. having its headquarter in Segrate (MI) Italy, Via Garibaldi 18, manufacturer of the group of devices named "immunochemistry kits"
Declares, under its own responsibility that the devices

Internal code: DKO 001	Description: CORTISOL ELISA	Edma Code: 1206020400
Internal code: DKO 002	Description: TESTOSTERONE ELISA	Edma Code: 1205011000
Internal code: DKO 003	Description: ESTRADIOL ELISA	Edma Code: 1205010300
Internal code: DKO 004	Description: 17OH PROGESTERONE ELISA	Edma Code: 1205010700
Internal code: DKO 005	Description: DHEA-S ELISA	Edma Code: 1205010200
Internal code: DKO 006	Description: PROGESTERONE ELISA	Edma Code: 1205010600
Internal code: DKO 007	Description: FREE ESTRIOL ELISA	Edma Code: 1205020300
Internal code: DKO 008	Description: ANDROSTENEDIONE ELISA	Edma Code: 1205010100
Internal code: DKO 009	Description: LH ELISA	Edma Code: 1205010500
Internal code: DKO 010	Description: FSH ELISA	Edma Code: 1205010400
Internal code: DKO 011	Description: PROLACTIN ELISA	Edma Code: 1205010800
Internal code: DKO 012	Description: AFP ELISA	Edma Code: 1203900100
Internal code: DKO 013	Description: TSH ELISA	Edma Code: 1204011000
Internal code: DKO 014	Description: b-HCG ELISA	Edma Code: 1205020600
Internal code: DKO 015	Description: FREE TESTOSTERONE ELISA	Edma Code: 1205011000
Internal code: DKO 016	Description: CIC C1Q ELISA	Edma Code: 1201020100
Internal code: DKO 017	Description: CIC C3D ELISA	Edma Code: 1201020300
Internal code: DKO 018	Description: URINARY CORTISOL ELISA	Edma Code: 1206020400
Internal code: DKO 019	Description: TOTAL ESTRIOL ELISA	Edma Code: 1205020200
Internal code: DKO 020	Description: CORTISOL SALIVA ELISA	Edma Code: 1206020400
Internal code: DKO 021	Description: TESTOSTERONE SALIVA ELISA	Edma Code: 1205011000
Internal code: DKO 022	Description: ESTRADIOL SALIVA ELISA	Edma Code: 1205010300
Internal code: DKO 023	Description: 17OH Progesterone SALIVA ELISA	Edma Code: 1205010700
Internal code: DKO 024	Description: DHEA-S SALIVA ELISA	Edma Code: 1205010200
Internal code: DKO 025	Description: PROGESTERONE SALIVA ELISA	Edma Code: 1205010600
Internal code: DKO 026	Description: ESTRIOL SALIVA ELISA	Edma Code: 1205020300
Internal code: DKO 027	Description: ANDROSTENEDIONE ELISA	Edma Code: 1205010100
Internal code: DKO 031	Description: CIC IGA ELISA	Edma Code: 1201020300
Internal code: DKO 033	Description: CIC IGG ELISA	Edma Code: 1201020300
Internal code: DKO 034	Description: CIC IGM ELISA	Edma Code: 1201020300
Internal code: DKO 037	Description: FT3 ELISA	Edma Code: 1204010100
Internal code: DKO 038	Description: FT4 ELISA	Edma Code: 1204010200
Internal code: DKO 039	Description: FERRITIN	Edma Code: 1207010200
Internal code: DKO 040	Description: CIC CH50 ELISA	Edma Code: 1201021100
Internal code: DKO 041	Description: CIC C3Bi ELISA	Edma Code: 1201020300

di conformità ai sensi "UNI CEI EN 45014 "Criteri generali per la dichiarazione di conformità rilasciata dal fornitore"

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Internal code: DKO 044	Description: T3 ELISA	Edma Code: 1204010300
Internal code: DKO 045	Description: T4 ELISA	Edma Code: 1204010400
Internal code: DKO 046	Description: ANTI TG ELISA	Edma Code: 1210030400
Internal code: DKO 047	Description: ANTI TPO ELISA	Edma Code: 1210030400
Internal code: DKO 048	Description: TG ELISA	Edma Code: 1204010800
Internal code: DKO 050	Description: HGH ELISA	Edma Code: 1206040200
Internal code: DKO 051	Description: CEA ELISA	Edma Code: 1203013100
Internal code: DKO 052	Description: PAP ELISA	Edma Code: 1203013700
Internal code: DKO 053	Description: ALDOSTERONE ELISA	Edma Code: 1206020100
Internal code: DKO 054	Description: CA125 ELISA	Edma Code: 1203010600
Internal code: DKO 055	Description: CA 15-3 ELISA	Edma Code: 1203010200
Internal code: DKO 056	Description: CA 19-9 ELISA	Edma Code: 1203010300
Internal code: DKO 057	Description: B2MICROGLOBULIN ELISA	Edma Code: 1203900200
Internal code: DKO 060	Description: IgE TOTAL ELISA	Edma Code: 1202010200
Internal code: DKO 067	Description: SALIVA CONTROL	Edma Code: 1205013000
Internal Code : DKO 068	Description: ESTRONE ELISA	Edma Code: 1205020400
Internal code: DKO 069	Description: CONTROL Plus Immunoassay and Tumor Marker	Edma Code: 1205013000
Internal code: DKO 073	Description: hNSE ELISA	Edma Code: 1203900800
Internal code: DKO 074	Description: S100B ELISA	Edma Code: 1203901800
Internal code: DKO 076	Description: INSULIN ELISA	Edma Code: 1206010300
Internal code: DKO 077	Description: C-PEPTIDE ELISA	Edma Code: 1206010100
Internal code: DKO 078	Description: IgA saliva ELISA	Edma Code: 1201010100
Internal code: DKO 079	Description: Microalbumin	Edma Code: 1201030100
Internal code: DKO 081	Description: HbA1C	Edma Code: 1206010600
Internal code: DKO 082	Description: Anti-GAD	Edma Code: 1206010500
Internal code: DKO 083	Description: IAA	Edma Code: 1206010400
Internal code: DKO 084	Description: IA2	Edma Code: 1206010700
Internal code: DKO 087	Description: SHBG	Edma Code: 1205010900

First Lot launched on the market: 02/11/1998

Comply with all the essential requirements listed in Annex I of directive 98/79/EC, as prescribed in

the Annex III of Directive 98/79/EC for the in vitro Medical Diagnostic Device and yours Italian assorbition issue from legislative decree 332/2000.

It therefore declares and assures, under its own responsibility, what here below expressed:

1. the devices of this list complies with the applicable provision of 98/79/EC Directive
2. the devices of this list are not included in the list A and B of the Annex II of Directive.
3. it's Diametra availability in preserving and in putting at the disposal of the competent authority the di conformità ai sensi "UNI CEI EN 45014 "Criteri generali per la dichiarazione di conformità rilasciata dal fornitore"

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Technical Documentation of the product , as specified in the Annex III of Directive 98/79/EC

4. the registration of the production and the related batch records will be stored for a period of at least five years from the last date of production of the last manufactured batch.
5. the IVD device, object of the following declaration, has been projected, produced and placed on the market with an introduction date prior to the date of this letter according to the Company Quality System, in compliance with standard ISO 13485 certified by BSI, as per indication expressed in the Annex III of a.m. directive

The declaration of conformity is valid for maximum 5 years

The manufacturer declares to have established a procedure and to maintain it in order to assure the post-marketing surveillance to the 98/79/EC Directive

Rev. 4 Date: July 5th, 2007

In faith

Capocciuti Feliciano

COO