



"CE" DECLARATION OF CONFORMITY

(Doc. DDC000-27)

The undersigned Dia.Metra S.r.l., with legal address and operation site at "via Pozzuolo 14, 06038 Spello, Italy", VAT N. 12585340156, hereby declares that the product:

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| Product Code: DKO001 | Product Name: Cortisol ELISA | Edma Code: 12.06.02.04 |
| Product Code: DKO002 | Product Name: Testosterone ELISA | Edma Code: 12.05.01.10 |
| Product Code: DKO003 | Product Name: Estradiol ELISA | Edma Code: 12.05.01.03 |
| Product Code: DKO004 | Product Name: 17OH Progesterone ELISA | Edma Code: 12.05.01.07 |
| Product Code: DKO005 | Product Name: DHEA-S ELISA | Edma Code: 12.05.01.02 |
| Product Code: DKO006 | Product Name: Progesterone ELISA | Edma Code: 12.05.01.06 |
| Product Code: DKO008 | Product Name: Androstenedione ELISA | Edma Code: 12.05.01.01 |
| Product Code: DKO009 | Product Name: LH ELISA | Edma Code: 12.05.01.05 |
| Product Code: DKO010 | Product Name: FSH ELISA | Edma Code: 12.05.01.04 |
| Product Code: DKO011 | Product Name: Prolactin ELISA | Edma Code: 12.05.01.08 |
| Product Code: DKO012 | Product Name: AFP ELISA | Edma Code: 12.03.90.01 |
| Product Code: DKO013 | Product Name: TSH ELISA | Edma Code: 12.04.01.11 |
| Product Code: DKO014 | Product Name: b-HCG ELISA | Edma Code: 12.05.02.06 |
| Product Code: DKO015 | Product Name: Free Testosterone ELISA | Edma Code: 12.05.01.10 |
| Product Code: DKO016 | Product Name: CIC C1q ELISA | Edma Code: 12.01.02.01 |
| Product Code: DKO017 | Product Name: CIC C3d ELISA | Edma Code: 12.01.02.03 |
| Product Code: DKO018 | Product Name: Urinary Cortisol ELISA | Edma Code: 12.06.02.04 |
| Product Code: DKO020 | Product Name: Cortisol saliva ELISA | Edma Code: 12.06.02.04 |
| Product Code: DKO021 | Product Name: Testosterone saliva ELISA | Edma Code: 12.05.01.10 |
| Product Code: DKO024 | Product Name: DHEA-S saliva ELISA | Edma Code: 12.05.01.02 |
| Product Code: DKO027 | Product Name: Androstenedione saliva ELISA | Edma Code: 12.05.01.01 |
| Product Code: DKO037 | Product Name: FT3 ELISA | Edma Code: 12.04.01.01 |
| Product Code: DKO038 | Product Name: FT4 ELISA | Edma Code: 12.04.01.02 |
| Product Code: DKO039 | Product Name: Ferritin ELISA | Edma Code: 12.07.01.02 |
| Product Code: DKO040 | Product Name: CH50 | Edma Code: 12.01.02.11 |
| Product Code: DKO044 | Product Name: T3 ELISA | Edma Code: 12.04.01.05 |
| Product Code: DKO045 | Product Name: T4 ELISA | Edma Code: 12.04.01.07 |
| Product Code: DKO048 | Product Name: Thyroglobulin ELISA | Edma Code: 12.04.01.08 |



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Numero REA: PG - 212096

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| Product Code: DKO050 | Product Name: HGH ELISA | Edma Code: 12.06.04.02 |
| Product Code: DKO051 | Product Name: CEA ELISA | Edma Code: 12.03.01.31 |
| Product Code: DKO053 | Product Name: Aldosterone ELISA | Edma Code: 12.06.02.01 |
| Product Code: DKO054 | Product Name: CA125 ELISA | Edma Code: 12.03.01.06 |
| Product Code: DKO055 | Product Name: CA 15-3 ELISA | Edma Code: 12.03.01.02 |
| Product Code: DKO056 | Product Name: CA 19-9 ELISA | Edma Code: 12.03.01.03 |
| Product Code: DKO060 | Product Name: IgE Total ELISA | Edma Code: 12.02.01.02 |
| Product Code: DKO073 | Product Name: hNSE ELISA | Edma Code: 12.03.90.08 |
| Product Code: DKO076 | Product Name: Insulin ELISA | Edma Code: 12.06.01.03 |
| Product Code: DKO077 | Product Name: C-Peptide ELISA | Edma Code: 12.06.01.01 |
| Product Code: DKO078 | Product Name: IgA saliva ELISA | Edma Code: 12.01.01.01 |
| Product Code: DKO082 | Product Name: Anti GAD | Edma Code: 12.06.01.05 |
| Product Code: DKO084 | Product Name: IA2 | Edma Code: 12.06.01.07 |
| Product Code: DKO085 | Product Name: TSH Receptor Ab | Edma Code: 12.10.03.03 |
| Product Code: DKO087 | Product Name: SHBG | Edma Code: 12.05.01.09 |
| Product Code: DKO091 | Product Name: Anti PR-3 (c-ANCA) | Edma Code: 12.10.90.10 |
| Product Code: DKO092 | Product Name: Anti MPO (p-ANCA) | Edma Code: 12.10.90.09 |
| Product Code: DKO095 | Product Name: Anti dsDNA IgG | Edma Code: 12.10.01.05 |
| Product Code: DKO099 | Product Name: ANA SCREEN | Edma Code: 12.10.01.01 |
| Product Code: DKO106 | Product Name: Anti Deamidated Gliadin Peptide (DGP) IgG | Edma Code: 12.10.90.06 |
| Product Code: DKO107 | Product Name: Anti Deamidated Gliadin Peptide (DGP) IgA | Edma Code: 12.10.90.06 |
| Product Code: DKO108 | Product Name: Anti Tissue Transglutaminase IgA | Edma Code: 12.10.90.21 |
| Product Code: DKO109 | Product Name: Anti Tissue Transglutaminase IgG | Edma Code: 12.10.90.21 |
| Product Code: DKO110 | Product Name: Anti beta 2 Glycoprotein 1 IgG | Edma Code: 12.10.90.04 |
| Product Code: DKO111 | Product Name: Anti beta 2 Glycoprotein 1 IgM | Edma Code: 12.10.90.04 |
| Product Code: DKO112 | Product Name: Anti Cardiolipin IgM | Edma Code: 12.10.90.01 |
| Product Code: DKO113 | Product Name: Anti Cardiolipin IgG | Edma Code: 12.10.90.01 |
| Product Code: DKO114 | Product Name: Anti Phospholipid Screen | Edma Code: 11.02.01.24 |
| Product Code: DKO115 | Product Name: Anti TG ELISA | Edma Code: 12.10.03.04 |
| Product Code: DKO116 | Product Name: Anti TPO ELISA | Edma Code: 12.10.03.01 |
| Product Code: DKO124 | Product Name: DHEA | Edma Code: 12.05.01.02 |
| Product Code: DKO137 | Product Name: Total PSA | Edma Code: 12.03.01.32 |



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| Product Code: DKO138 | Product Name: Free PSA | Edma Code: 12.03.01.33 |
| Product Code: DKO144 | Product Name: Anti Cardiolipin Screen | Edma Code: 12.10.90.01 |
| Product Code: DKO145 | Product Name: Anti beta 2 Glycoprotein 1 Screen | Edma Code: 12.10.90.04 |
| Product Code: DKO146 | Product Name: 25OH Vitamin D | Edma Code: 12.06.03.10 |
| Product Code: DKO149 | Product Name: Anti CP IgG | Edma Code: 12.10.01.03 |
| Product Code: DKO157 | Product Name: Intact PTH ELISA | Edma Code: 12.06.03.13 |
| Product Code: DKO186 | Product Name: IGF-1 | Edma Code: 12.06.04.03 |

documented by the technical files archived in the Regulatory Affairs department:

- is an in vitro diagnostic medical device including reagents and calibrators, intended for use in vitro to test human serum - plasma - saliva - urine samples (depending on the kit), according to the definition given in art. 1 par. 2b of the Directive 98/79/EC and according to a certified Quality System Management ISO 13485:2016 & EN ISO 13485:2016;
- does not include sterile components;
- is not intended for self-diagnosis;
- is not intended for performance evaluation;
- uses the most advanced methods;
- Country of Origin: Italy.

Classification: the product

- is "other IVDD" (Non Annex II, Non Self Testing, For Professional Use, Self Declaration - see Note 1 for PSA products)
- meets the essential requirements of Annex I to the aforementioned Directive;
- is not included in the Annex II to the aforementioned Directive (see Note 1 for PSA products);
- meets the requirements of the harmonized standards required by the EC Directive.

The undersigned:

- complies with the provisions of Annex III (CE Declaration of Conformity) to the aforementioned Directive to affix the CE marking on the labeling of the device (see Note 1);
- is committed to keep in place and up to date a procedure to review experience gained from device in the post-production phase, according to the provisions of Annex III, section 5, to the aforementioned Directive, on the basis of the feed-back from the market;
- is committed to set up and keep available to the competent Authorities the technical documentation as specified in Annex III, section 3, for a period ending at least ten years after the last product has been manufactured.



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Note 1: Total PSA (DKO137) and Free PSA (DKO138) kits are included in the Annex II List B to the aforementioned Directive, thus CE mark is released by BSI, Say Building, John M. Keynesplein 9, 1066EP Amsterdam, The Netherlands, Code CE2797, according to Annex IV to the aforementioned Directive.

Spello (PG), 2022 May 23rd

Massini Carlo
(Regulatory Affairs Manager)


Carlo Massini
DIA.METRA S.r.l.
Authorized Representative

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