Dia.Metra Srl
Cap.Soc. € 96.000,00 i.v.
Codice Fiscale 02190680542 - Partita Iva IT 12585340156
Numero REA: PG - 212096

"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 products:

n°	Product Code	Product Name	EMDN Code
1.	DKO001	Cortisol ELISA	W0102060203
2.	DKO002	Testosterone ELISA	W0102050110
3.	DKO003	Estradiol ELISA	W0102050103
4.	DKO004	17OH Progesterone ELISA	W0102050107
5.	DKO005	DHEA-S ELISA	W0102050102
6.	DKO006	Progesterone ELISA	W0102050106
7.	DKO008	Androstenedione ELISA	W0102050101
8.	DKO009	LH ELISA	W0102050105
9.	DKO010	FSH ELISA	W0102050104
10.	DKO011	Prolactin ELISA	W0102050108
11.	DKO012	AFP ELISA	W0102039001
12.	DKO013	TSH ELISA	W01020410
13.	DKO014	b-HCG ELISA	W0102050213
14.	DKO015	Free Testosterone ELISA	W0102050110
15.	DKO016	CIC C1q ELISA	W0102010201
16.	DKO018	Urinary Cortisol ELISA	W0102060203
17.	DKO020	Cortisol saliva ELISA	W0102060203
18.	DKO021	Testosterone saliva ELISA	W0102050110
19.	DKO024	DHEA-S saliva ELISA	W0102050102
20.	DKO027	Androstenedione saliva ELISA	W0102050101
21.	DKO037	FT3 ELISA	W01020401
22.	DKO038	FT4 ELISA	W01020402
23.	DKO039	Ferritin ELISA	W0102070102
24.	DKO040	CH50	W0102010208
25.	DKO044	T3 ELISA	W01020405
26.	DKO045	T4 ELISA	W01020407
27.	DKO048	Thyroglobulin ELISA	W01020408
28.	DKO050	HGH ELISA	W0102060402
29.	DKO051	CEA ELISA	W0102030112
30.	DKO053	Aldosterone ELISA	W0102060201

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31.	DKO054	CA125 ELISA	W0102030106
32.	DKO055	CA 15-3 ELISA	W0102030102
33.	DKO056	CA 19-9 ELISA	W0102030103
34.	DKO060	IgE Total ELISA	W01020201
35.	DKO073	hNSE ELISA	W0102039007
36.	DKO076	Insulin ELISA	W0102060103
37.	DKO077	C-Peptide ELISA	W0102060101
38.	DKO078	IgA saliva ELISA	W0102010101
39.	DKO082	Anti GAD	W0102060105
40.	DKO084	IA2	W0102060106
41.	DKO085	TSH Receptor Ab	W0102100302
42.	DKO087	SHBG	W0102050109
43.	DKO091	Anti PR-3 (c-ANCA)	W0102100403
44.	DKO092	Anti MPO (p-ANCA)	W0102100402
45.	DKO095	Anti dsDNA IgG	W0102100105
46.	DKO099	ANA SCREEN	W0102100101
47.	DKO106	Anti Deamidated Gliadin Peptide (DGP) IgG	W0102100604
48.	DKO107	Anti Deamidated Gliadin Peptide (DGP) IgA	W0102100604
49.	DKO108	Anti Tissue Transglutaminase IgA	W0102100601
50.	DKO109	Anti Tissue Transglutaminase IgG	W0102100601
51.	DKO110	Anti beta 2 Glycoprotein 1 IgG	W0102100503
52.	DKO111	Anti beta 2 Glycoprotein 1 IgM	W0102100503
53.	DKO112	Anti Cardiolipin IgM	W0102100501
54.	DKO113	Anti Cardiolipin IgG	W0102100501
55.	DKO114	Anti Phospholipid Screen	W0103020601
56.	DKO115	Anti TG ELISA	W0102100303
57.	DKO116	Anti TPO ELISA	W0102100301
58.	DKO124	DHEA	W0102050102
59.	DKO144	Anti Cardiolipin Screen	W0102100501
60.	DKO145	Anti beta 2 Glycoprotein 1 Screen	W0102100503
61.	DKO146	25OH Vitamin D	W0102060309
62.	DKO149	Anti CP IgG	W01021199
63.	DKO157	Intact PTH ELISA	W0102060312
64.	DKO186	IGF-1	W0102060403

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

- are in vitro diagnostic medical devices 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 EN ISO 13485:2016;
- do not include sterile components;
- are not intended for self-diagnosis;
- are not intended for performance evaluation;
- use the most advanced methods;
- Country of Origin: Italy.

Classification: the products

- are "other IVDD" (Non Annex II, Non Self Testing, For Profesional Use, Self Declaration)
- meet the essential requirements of Annex I to the aforementioned Directive;
- are not included in the Annex II to the aforementioned Directive;
- meet 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;
- 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 five years after the last product has been manufactured.

Spello (PG), 2022 May 23rd

Massini Carlo
(Regulatory Affairs Manager)

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

DIA.METRA S.r.l. Unipersonale
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