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**DECLARATION OF CONFORMITY**

According to Annex III of the Directive 98/79/EC for in vitro diagnostic medical devices, of the European Council, we

♦ **Manufacturer** **Camp Medica Distribution SRL**
Str. Stănei no. 29, Sector 4, Bucharest – Romania

declare under our sole responsibility that the following IVD medical device,

♦ **Product name** **Trust Me** in vitro diagnostic rapid tests – see Annex 1,

meet the provisions of the European Directive 98/79/EC, concerning in vitro diagnostic medical devices, which apply to them.

♦ **Requests** European Directive no. 98/79/CE from October 27th, of the European Parliament Council for in vitro diagnostic medical devices

♦ **Conformity assessment route** Annex III (from European Directive 98/79/CE), sections 2 to 5

♦ **Classification** medical devices for in vitro diagnostic (IVDD)
EDMA Code : see annex

The following standards were used to prove the products conformity with the essential requirements of the above directive: **SR EN ISO 13485:2012.**

♦ **Standards Applied** EN 375: 2001, EN 980: 2003, EN 13612: 2002, EN 13640:2002,
EN 13641:2002, SR EN ISO 14971:2007, SR EN ISO 13485:2012

♦ **Place, Date of Issue** Bucharest – Romania, 05.01.2017

Quality Manager

Dr. Eng. Carolina Constantin

CODE	PRODUCT NAME	Format	Risk Class	EDMS code
1.	Pregnancy/ Fertility			
TM 1.1/TM 1.2	hCG urine	Strip/Cassette	Low risk	12 70 05 02 00
TM 1.1'/TM1.2'	hCG combo urine/serum	Strip/Cassette	Low risk	12 70 05 02 00
TM 1.2"	hCG urine	Pen (midstream)	Low risk	12 70 05 02 00
TM 1.3/TM1.4	LH urine	Strip/ Cassette	Low risk	12 70 05 04 00
TM 1.5/TM1.6	FSH urine	Strip/ Cassette	Low risk	12 70 05 01 00
2.	Infectious diseases			
TM 2.2	H. Pylori WB/serum/plasma	Cassette	Low risk	15 70 01 02 00
TM 2.2'	H. Pylori Antigen stool (feces)	Cassette	Low risk	15 70 01 02 00
3.	Tumor Markers			
TM 3.1/TM3.2	AFP-Alpha Fetoprotein S/P	Strip/ Cassette	Low risk	12 70 03 90 00
TM 3.3/TM3.4	CEA-Carcinoma Embryonic Ag. S/P	Strip/ Cassette	Low risk	12 70 03 90 00
TM 3.7	FOB - feces	Cassette	Low risk	11 70 03 01 00
4.	Sexually transmitted diseases			
TM 4.1/TM4.2	Syphilis serum/plasma	Strip/ Cassette	Low risk	15 70 01 05 00
TM 4.4	Gonorrhea swab	Cassette	Low risk	15 70 01 90 00
6.	Cardiac Markers			
TM 6.1	Troponin I WB/serum/plasma	Cassette	Low risk	12 70 13 03 00
TM 6.2	Myoglobin WB/serum/plasma	Cassette	Low risk	12 70 13 02 00
TM 6.3	CK-MB WB/serum/plasma	Cassette	Low risk	12 70 13 01 00
TM 6.X.3	3 cardiac tests (cTnI, CK-MB, Myo) panel	Cassette	Low risk	
7.	DOA (Drugs Of Abuse)			
TM 7.1	AMP urine	Strip / Cassette	Low risk	12 70 09 01 00
TM 7.2	BAR urine	Strip / Cassette	Low risk	12 70 09 03 00
TM 7.3	BZO urine	Strip / Cassette	Low risk	12 70 09 04 00
TM 7.4	COC urine	Strip / Cassette	Low risk	12 70 09 06 00
TM 7.5	MDMA urine	Strip / Cassette	Low risk	12 70 09 90 00
TM 7.6	MET urine	Strip / Cassette	Low risk	12 70 09 90 00
TM 7.7	MOP urine	Strip / Cassette	Low risk	12 70 09 08 00
TM 7.8	MTD urine	Strip / Cassette	Low risk	12 70 09 07 00
TM 7.9	OPI urine	Strip / Cassette	Low risk	12 70 09 08 00
TM 7.10	TCA urine	Strip / Cassette	Low risk	12 70 09 10 00
TM 7.11	THC urine	Strip / Cassette	Low risk	12 70 09 05 00
TM 7.12	PCP urine	Strip / Cassette	Low risk	12 70 09 09 00
TM 7.13	BUP urine	Strip / Cassette	Low risk	12 70 09 90 00
TM 7.14	OXY urine	Strip / Cassette	Low risk	12 70 09 90 00
TM 7.15	POX urine	Strip / Cassette	Low risk	12 70 09 90 00
TM 7.16	TRA urine	Strip / Cassette	Low risk	12 70 09 90 00
TM 7.17	K2 urine	Strip / Caseta	Low risk	12 70 09 90 00
TM 7.X.2	2 DOA panel urine	Plastic device	Low risk	12 70 09 70 00
TM 7.X.3	3 DOA panel urine	Plastic device	Low risk	12 70 09 70 00
TM 7.X.4	4 DOA panel urine	Plastic device	Low risk	12 70 09 70 00
TM 7.X.5	5 DOA panel urine	Plastic device	Low risk	12 70 09 70 00
TM 7.X.10	10 DOA panel urine	Plastic device	Low risk	12 70 09 70 00
TM 7.X.10	10 DOA panel (K2)	Plastic device	Low risk	12 70 09 70 00
TM 7.X.12	12 DOA panel urine	Plastic device	Low risk	12 70 09 70 00
TM 7.X.12	12 DOA panel (K2)	Plastic device	Low risk	12 70 09 70 00
8.	Parasitology			
TM 8.1	Malaria pf whole blood	Cassette	Low risk	14 05 02 02 00
TM 8.1'	Malaria pf/pv whole blood	Cassette	Low risk	14 05 02 02 00
TM 8.2	Dengue IgG/IgM Ab	Cassette	Low risk	15 04 80 11 00
TM 8.3	Dengue NS1 Ag.	Cassette	Low risk	15 04 80 11 00
9.	Microbiology		Low risk	
TM 9.1	Tuberculosis WB/S/P	Cassette	Low risk	15 01 07 03 00
11.	Bacteriology		Low risk	
TM 11.1	Tetanus WB/S/P	Cassette	Low risk	15 01 40 09 00
12.	Toxicology		Low risk	
TM 12.1	Alcohol urine/saliva	Strip	Low risk	12 09 02 07 00

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