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## DECLARATION OF CONFORMITY

**Manufacturer's Name:** Cell Marque Corporation  
**Business Address:** 6600 Sierra College Boulevard  
Rocklin, CA 95677  
United States of America

**European -**

**Authorized Representative:** EMERGO EUROPE

**Address -**

**Authorized Representative:** Molenstraat 15  
2513 BH, The Hague  
The Netherlands  
Phone: +31.70.345.8570  
Fax: +31.70.346.7299

**Scope of Application:** Cell Marque reagents and control slides used for performing immunohistochemistry tests to evaluate human formalin fixed tissues. See appendix list of products

**Classification:** Annex III Self-Certified IVD, not listed in Annex II list A or B.

**Standards applied:** ISO 13485:2003 CMDCAS

**Full Quality Management System Certificate:**

ISO 13485:2003 CMDCAS  
Dekra Certification B.V.  
Certificate Number 550292

Cell Marque Corporation declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

**Authorized Signatory:**

  
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Veronica Runyan, V.P., Regulatory & Quality Affairs

  
\_\_\_\_\_  
Date

Ventana Catalog No.	Roche Catalog No.	Item Description Identification	EDMA	GMDN Code
760-2708	05268176001	ACTH Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-2601	05267161001	Actin, Muscle Specific (HHF35) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-2833	05268303001	Actin, Smooth Muscle (1A4) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4870	07047762001	Adenovirus (2/6 & 20/11) Mouse Monoclonal Primary Antibody	15.04.80.01.00	0
760-2603	05267188001	Alpha-Fetoprotein Rabbit Polyclonal Antibody	12.03.90.01.00	30295
760-2604	05267196001	A-1-Antichymotrypsin Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-2605	05267200001	A-1-Antitrypsin Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-4605	06523838001	anti-Androgen Receptor (SP107) Rabbit Monoclonal Primary Antibody	12.03.02.90.00	0
760-4435	05973945001	Annexin A1 (MRQ-3) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4801	06732348001	anti-Arginase-1 (SP156) Rabbit Monoclonal Primary Antibody	12.03.01.90.00	0
760-2607	05267226001	BCA-225 (Cu-18) Mouse Monoclonal Antibody	12.03.01.90.00	43825
760-4241	05269008001	bcl-6 (G1191E/A8) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4242	05269016001	Beta-Catenin (14) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4450	05973767001	BG8, Lewis Y (F3) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4593	06433308001	BOB.1 (SP92) Rabbit Monoclonal Antibody	12.03.90.90.00	0
760-4522	06419143001	C3d Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-4436	05973937001	C4d Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-4803	06732364001	anti-C4d (SP91) Rabbit Monoclonal Primary Antibody	12.03.90.90.00	0
760-2610	05267269001	CA-125 (OC125) Mouse Monoclonal Antibody	12.03.01.06.00	30283
760-2609	05267242001	CA19-9 (121SLE) Mouse Monoclonal Antibody	12.03.01.03.00	0
760-4865	07047703001	Cadherin 17 (SP183) Rabbit Monoclonal Primary Antibody	12.03.90.90.00	0
760-2611	05267277001	Calcitonin Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-4705	06586554001	anti-Calcitonin (SP17) Rabbit Monoclonal Primary Antibody	12.03.90.90.00	0
760-4375	05463459001	Caldesmon (E89) Rabbit Monoclonal Antibody	12.03.01.90.00	0
760-4376	05435684001	Calponin-1 (EP798Y) Rabbit Monoclonal Antibody	12.03.01.90.00	0
760-2705	05268141001	CD10 Mouse Monoclonal Antibody - Concentrated	12.03.90.90.00	0
760-4248	05269083001	CD138/syndecan-1 (B-A38) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4862	07047673001	CD13 (SP187) Rabbit Monoclonal Primary Antibody	12.03.90.90.00	0
760-4523	06419151001	CD14 (EPR3653) Rabbit Monoclonal Antibody	12.03.90.90.00	0
760-4863	07047681001	CD16 (SP175) Rabbit Monoclonal Primary Antibody	12.03.90.90.00	0
760-4437	05973929001	CD163 (MRQ-26) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4244	05269032001	CD1a (MTB1) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4525	06419160001	CD1a (EP3622) Rabbit Monoclonal Antibody	12.03.90.90.00	0
760-4377	05463467001	CD2 (MRQ-11) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4245	05269059001	CD21 (2G9) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4438	05973902001	CD21 (EP3093) Rabbit Monoclonal Antibody	12.03.90.90.00	0
760-4439	05973899001	CD25 (4C9) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4378	05463475001	CD31 (JC70) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-2620	05267323001	CD34 (QBEnd/10) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4785	06648550001	anti-CD38 (SP149) Rabbit Monoclonal Primary Antibody	12.03.90.90.00	0
760-4279	05269423001	CD45 (LCA) (2B11 & PD7/26) Mouse Monoclonal Antibody	12.03.90.90.00	0

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760-2624	05267340001	CD45R (MB1) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-2625	05267358001	CD56 (123C3.D5) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4596	06433359001	CD56 (MRQ-42) Rabbit Monoclonal Antibody	12.03.90.90.00	0
760-2626	05267366001	CD57 (NK-1) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4249	05269091001	CD61 (2f2) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4379	05463483001	CD63 (NK1/C3) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4589	06433162001	CD71 (MRQ-48) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-2628	05267374001	CD74 (LN2) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4380	05463491001	CDX-2 (EPR2764Y) Rabbit Monoclonal Antibody	12.03.01.90.00	0
760-4594	06433316001	CEA (CEA31) Mouse Monoclonal Antibody	12.03.01.31.00	17293
760-2632	05267439001	Collagen Type IV (CIV22) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4254	05269148001	COX-2 (SP21) Rabbit Monoclonal Antibody	12.03.90.90.00	0
760-4282	05269458001	Cyclin D1 (SP4) Rabbit Monoclonal Antibody	12.03.90.90.00	0
760-2637	05267471001	Cytokeratin (35betaH11) Mouse Monoclonal Antibody	12.03.01.90.00	34007
760-4935	07292821001	Cytokeratin 5 (SP27) Rabbit Monoclonal Primary Antibody	12.03.01.90.00	34007
760-4251	05269113001	Cytokeratin 14 (LL002) Mouse Monoclonal Antibody	12.03.01.90.00	34007
760-4805	06732429001	anti-Cytokeratin 14 (SP53) Rabbit Monoclonal Primary Antibody	12.03.01.90.00	34007
760-4281	05269440001	Cytokeratin 19 (A53-B/A2.26) Mouse Monoclonal Antibody	12.03.01.90.00	30287
760-4253	05269130001	Cytokeratin 5 & 6 (D5 & 16B4) Mouse Monoclonal Antibody	12.03.01.90.00	34007
760-4939	07292864001	Cytokeratin 5/14 (EP1601Y/LL002) Rabbit and Mouse Monoclonal Primary Antibody	12.03.01.90.00	34007
760-4344	05269776001	Cytokeratin 8 & 18 (B22.1 & B23.1) Mouse Monoclonal Antibody	12.03.01.90.00	34007
760-4590	06433189001	DOG1 (SP31) Rabbit Monoclonal Antibody	12.03.90.90.00	0
760-4440	05973872001	E-Cadherin (EP700Y) Rabbit Monoclonal Antibody	12.03.01.90.00	0
760-4259	05269202001	EMA (E29) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4383	05435676001	Ep-CAM/Epithelial Specific Antigen (Ber-EP4) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-2640	05267501001	Epstein Barr Virus (CS1-4) Mouse Monoclonal Antibody	15.04.04.04.00	17339
760-2642	05267528001	Factor VIII-R Ag Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-4384	05435692001	Factor XIIIa (AC-1A1) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4441	05922470001	Factor XIIIa (EP3372) Rabbit Monoclonal Antibody	12.03.90.90.00	0
760-2702	05268117001	Fascin (55k-2) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4937	07292848001	FOXA1 (2F83) Mouse Monoclonal Primary Antibody	12.03.01.90.00	0
760-4611	06548938001	anti-FoxP1 (SP133) Rabbit Monoclonal Primary Antibody	12.03.90.90.00	0
760-2710	05268192001	FSH Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-4256	05269164001	Galectin-3 (9C4) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-2643	05267536001	Gastrin Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-4897	07107749001	GATA3 (L50-823) Mouse Monoclonal Primary Antibody	12.03.01.90.00	0
760-4386	05463530001	GCDFP-15 (EP1582Y) Rabbit Monoclonal Antibody	12.03.01.90.00	0
760-4345	05269784001	Glial Fibrillary Acidic Protein (EP672Y) Rabbit Monoclonal Antibody	12.03.90.90.00	0
760-2804	05268257001	GH (Growth Hormone) Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-2644	05267544001	Glucagon Rabbit Polyclonal Antibody	12.03.90.90.00	0

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760-4526	06419178001	GLUT1 Rabbit Polyclonal Antibody	12.03.01.90.00	0
760-4898	07107757001	Glutamine Synthetase (GS-6) Mouse Monoclonal Primary Antibody	12.03.90.90.00	0
760-4257	05269172001	Glycophorin-A (GA-R2) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4442	05973864001	Glypican-3 (1G12) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4283	05269466001	Granzyme B Rabbit Polyclonal Antibody Prediluted	12.03.90.90.00	0
760-2645	05267552001	Helicobacter pylori Rabbit Polyclonal Antibody	15.01.04.03.00	30691
760-2650	05267617001	hCG Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-4936	07292830001	Hemoglobin A (SP212) Rabbit Monoclonal Primary Antibody	12.03.90.90.00	0
760-4350	05269792001	Hepatocyte Specific Antigen (OCH1E5) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4597	06433375001	HGAL (MRQ-49) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4260	05269229001	HHV-8 (13B10) Mouse Monoclonal Antibody	15.04.80.24.00	0
760-4261	05269237001	Herpes Simplex Virus I Rabbit Polyclonal Antibody	15.04.03.07.00	17363
760-4869	07047746001	Herpes Simplex Virus I (10A3) Mouse Monoclonal Primary Antibody	14.04.03.07.00	17363
760-4262	05269245001	Herpes Simplex Virus II Rabbit Polyclonal Antibody	15.04.03.10.00	17363
760-4443	05973830001	Human Placental Lactogen (hPL) Rabbit Polyclonal Antibody	12.03.01.90.00	0
760-2652	05267625001	IgA Rabbit Polyclonal Antibody	12.01.01.01.00	17369
760-4444	05973821001	IgD Rabbit Polyclonal Antibody	12.01.01.03.00	17370
760-2653	05267633001	IgG Rabbit Polyclonal Antibody	12.01.01.05.00	17372
760-4614	06523854001	anti-IgG4 (MRQ-44) Mouse Monoclonal Primary Antibody	12.01.01.06.00	39022
760-2654	05267641001	IgM Rabbit Polyclonal Antibody	12.01.01.07.00	17373
760-2834	05268311001	Inhibin, alpha (R1) Mouse Monoclonal antibody	12.03.01.90.00	0
760-4615	06523862001	anti-INI-1 (MRQ-27) Mouse Monoclonal Primary Antibody	12.03.90.90.00	0
760-2655	05267650001	Insulin Guinea Pig Polyclonal Antibody	12.03.90.90.00	0
760-4387	05463548001	Ksp-Cadherin (MRQ-33) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-2802	05268222001	LH Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-4704	06586546001	anti-LMO2 (SP51) Rabbit Monoclonal Primary Antibody	12.03.90.90.00	0
760-2656	05267668001	Lysozyme Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-2657	05267676001	Macrophage (HAM-56) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4263	05269253001	Mammaglobin (31A5) Rabbit Monoclonal Antibody	12.03.01.90.00	0
760-4527	06419186001	Melanoma Associated Antigen (KBA.62) Mouse Monoclonal Antibody-Prediluted	12.03.90.90.00	0
760-4528	06419194001	Melanoma Associated Antigen (PNL2) Mouse Monoclonal Antibody-Prediluted	12.03.90.90.00	0
760-4445	05973813001	Mesothelial Cell (HBME-1) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4264	05269261001	MLH-1 (G168-728) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4265	05269270001	MSH2 (G219-1129) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4388	05463556001	MUC2 (MRQ-18) Mouse Monoclonal Antibody	12.03.01.90.00	30289
760-4389	05463564001	MUC5AC (MRQ-19) Mouse Monoclonal Antibody	12.03.01.90.00	30289
760-4390	05463572001	MUC6 (MRQ-20) Mouse Monoclonal Antibody	12.03.01.90.00	30289
760-4529	06419208001	MUM1 (MRQ-43) Rabbit Monoclonal Antibody	12.03.90.90.00	0
760-2658	05267684001	Myelin Basic Protein Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-2659	05267692001	Myeloperoxidase Rabbit Polyclonal Antibody	12.03.90.90.00	0

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760-4900	07107773001	MyoD1 (EP212) Rabbit Monoclonal Primary Antibody	12.03.90.90.00	0
760-2832	05268290001	Myogenin (F5D) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-2660	05267706001	Myoglobin Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-2704	05268133001	Myosin, Smooth Muscle (SMMS-1) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4867	07047720001	Napsin A (MRQ-60) Mouse Monoclonal Primary Antibody	12.03.01.90.00	0
760-4446	05973805001	Napsin A Rabbit Polyclonal Antibody	12.03.01.90.00	0
760-4391	05463599001	NGFR (Nerve Growth Factor Receptor) (MRQ-21) Mouse Monoclonal Antibody	12.03.02.90.00	0
760-2661	05267714001	Neurofilament (2F11) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4786	06648568001	anti-NSE (MRQ-55) Mouse Monoclonal Primary Antibody	12.03.90.08.00	30301
760-4447	05973791001	OCT2 (MRQ-2) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4392	05463602001	OCT4 (MRQ-10) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4453	05973961001	p21/WAF1 (DCS-60.2) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4268	05269300001	p27/Kip1 (SX53G8) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4617	06523897001	anti-p57/Kip2 (Kp10) Mouse Monoclonal Primary Antibody	12.03.90.90.00	0
760-4532	06419224001	Parathyroid Hormone (PTH) (MRQ-31) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4393	05463629001	PAX-2 Rabbit Polyclonal Antibody	12.03.01.90.00	0
760-4618	06523927001	anti-PAX8 (MRQ-50) Mouse Monoclonal Primary Antibody	12.03.01.90.00	0
760-4448	05973783001	PD-1 (MRQ-22) Mouse Monoclonal Antibody	12.03.02.90.00	0
760-4895	07099029001	PD-1 (NAT105) Mouse Monoclonal Antibody	12.03.02.90.00	0
760-4394	05463637001	Perforin (MRQ-23) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4434	05973953001	PGP9.5 Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-4591	06433405001	Phosphohistone H3 Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-2664	05267757001	PLAP (NB10) Mouse Monoclonal Antibody	12.03.90.06.00	30299
760-4531	06419216001	PMS2 (EPR3947) Rabbit Monoclonal Antibody	12.03.01.90.00	0
760-2665	05267765001	Pneumocystis jiroveci (carinii) (3F6) Mouse Monoclonal Antibody	14.03.04.90.00	0
760-4395	05463645001	Podoplanin (D2-40) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-2803	05268249001	Prolactin Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-4272	05269342001	PSAP (PASE/4LJ) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4273	05269369001	Renal Cell Carcinoma (PN-15) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4620	06523935001	anti-S100P (16/f5) Mouse Monoclonal Primary Antibody	12.03.01.90.00	0
760-4864	07047690001	SALL4 (6E3) Mouse Monoclonal Primary Antibody	12.03.90.90.00	0
760-4592	06433278001	Smoothelin (R4A) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-2667	05267781001	Somatostatin Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-4621	06523943001	anti-SOX-2 (SP76) Rabbit Monoclonal Primary Antibody	12.03.01.90.00	0
760-4868	07047738001	SOX-11 (MRQ-58) Mouse Monoclonal Primary Antibody	12.03.90.90.00	0
760-4274	05269377001	Spectrin (RBC2/3D5) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4449	05973775001	SV40 (MRQ-4) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4595	06433324001	Synaptophysin (MRQ-40) Rabbit Monoclonal Antibody	12.03.90.90.00	0
760-4598	06433391001	T-bet (MRQ-46) Rabbit Monoclonal Antibody Prediluted	12.03.90.90.00	0

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760-2669	05267803001	TAG-72 (B72.3) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-2670	05267811001	TdT Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-4622	06523951001	anti-TFE3 (MRQ-37) Rabbit Monoclonal Primary Antibody	12.03.01.90.00	0
760-2671	05267820001	Thyroglobulin (2H11+6E1) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4275	05269385001	TRAcP (9C5) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-4276	05269393001	Tryptase (G3) Mouse Monoclonal Antibody	12.03.90.90.00	0
760-2709	05268184001	TSH Rabbit Polyclonal Antibody	12.03.90.90.00	0
760-4533	06419232001	Uroplakin III (SP73) Rabbit Monoclonal Antibody	12.03.01.90.00	0
760-4277	05269407001	Villin (CWWB1) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4397	05435706001	WT1 (6F-H2) Mouse Monoclonal Antibody	12.03.01.90.00	0
760-4278	05269415001	ZAP-70 (2F3.2) Mouse Monoclonal Antibody	12.03.90.90.00	0