

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product Name	Model/Number
See Attached List	See Attached List

MANUFACTURER		
Name of Company	Address	Representative
Cell Marque Corporation	6600 Sierra College Boulevard Rocklin, CA 95677 United States of America	Farhad Dashty

AUTHORIZED REPRESENTATIVE		
Name of Company	Address	Telephone/Email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

CONFORMITY ASSESSMENT		
Device Classification	Route to Compliance	Standards Applied
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	ISO 13485:2016

Cell Marque Corporation declares that the above mentioned/attached list of 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.

COMPANY REPRESENTATIVE: Jenifer Dawson Driscoll

TITLE: Sr. Specialist, Regulatory Affairs

SIGNATURE:

DATE: Mar 26, 2020



Merck KGaA

www.merckgroup.com

The life science business of Merck operates as MilliporeSigma in the U.S. and Canada.

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Form 7.5-1-7-6, Rev. 2
www.cellmarque.com

Ventana Catalog No.	Roche Catalog No.	Item Description Identification	EDMA
760-2708	05268176001	ACTH Rabbit Polyclonal Antibody	13.07.01.09
760-2601	05267161001	Actin, Muscle Specific (HHF35) Mouse Monoclonal Antibody	13.07.01.09
760-2833	05268303001	Actin, Smooth Muscle (1A4) Mouse Monoclonal Antibody	13.07.01.09
760-4870	07047762001	Adenovirus (2/6 & 20/11) Mouse Monoclonal Primary Antibody	13.07.01.09
760-2603	05267188001	Alpha-Fetoprotein Rabbit Polyclonal Antibody	13.07.01.09
760-2604	05267196001	A-1-Antichymotrypsin Rabbit Polyclonal Antibody	13.07.01.09
760-2605	05267200001	A-1-Antitrypsin Rabbit Polyclonal Antibody	13.07.01.09
760-4605	06523838001	anti-Androgen Receptor (SP107) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4435	05973945001	Annexin A1 (MRQ-3) Mouse Monoclonal Antibody	13.07.01.09
760-4801	06732348001	anti-Arginase-1 (SP156) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-2607	05267226001	BCA-225 (Cu-18) Mouse Monoclonal Antibody	13.07.01.09
760-4241	05269008001	bcl-6 (G1191E/A8) Mouse Monoclonal Antibody	13.07.01.09
760-4242	05269016001	Beta-Catenin (14) Mouse Monoclonal Antibody	13.07.01.09
760-4450	05973767001	BG8, LewisY (F3) Mouse Monoclonal Antibody	13.07.01.09
760-4593	06433308001	BOB.1 (SP92) Rabbit Monoclonal Antibody	13.07.01.09
760-4522	06419143001	C3d Rabbit Polyclonal Antibody	13.07.01.09
760-4436	05973937001	C4d Rabbit Polyclonal Antibody	13.07.01.09
760-4803	06732364001	anti-C4d (SP91) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-2610	05267269001	CA-125 (OC125) Mouse Monoclonal Antibody	13.07.01.09
760-2609	05267242001	CA19-9 (121SLE) Mouse Monoclonal Antibody	13.07.01.09
760-4865	07047703001	Cadherin 17 (SP183) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-2611	05267277001	Calcitonin Rabbit Polyclonal Antibody	13.07.01.09
760-4705	06586554001	anti-Calcitonin (SP17) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4375	05463459001	Caldesmon (E89) Rabbit Monoclonal Antibody	13.07.01.09
760-4376	05435684001	Calponin-1 (EP798Y) Rabbit Monoclonal Antibody	13.07.01.09
760-6080	08313466001	Carbonic Anhydrase IX (EP161) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4951	07391439001	Caveolin-1 (SP43) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4248	05269083001	CD138/syndecan-1 (B-A38) Mouse Monoclonal Antibody	13.07.01.09
760-4862	07047673001	CD13 (SP187) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4523	06419151001	CD14 (EPR3653) Rabbit Monoclonal Antibody	13.07.01.09
760-4863	07047681001	CD16 (SP175) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4437	05973929001	CD163 (MRQ-26) Mouse Monoclonal Antibody	13.07.01.09
760-4525	06419160001	CD1a (EP3622) Rabbit Monoclonal Antibody	13.07.01.09
760-4377	05463467001	CD2 (MRQ-11) Mouse Monoclonal Antibody	13.07.01.09
760-4245	05269059001	CD21 (2G9) Mouse Monoclonal Antibody	13.07.01.09
760-4438	05973902001	CD21 (EP3093) Rabbit Monoclonal Antibody	13.07.01.09
760-4439	05973899001	CD25 (4C9) Mouse Monoclonal Antibody	13.07.01.09
760-4378	05463475001	CD31 (JC70) Mouse Monoclonal Antibody	13.07.01.09
760-4952	07391447001	CD33 (SP266) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-2620	05267323001	CD34 (QBEnd/10) Mouse Monoclonal Antibody	13.07.01.09
760-4785	06648550001	anti-CD38 (SP149) Rabbit Monoclonal Primary Antibody	13.07.01.09

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760-4279	05269423001	CD45 (LCA) (2B11 & PD7/26) Mouse Monoclonal Antibody	13.07.01.09
760-2624	05267340001	CD45R (MB1) Mouse Monoclonal Antibody	13.07.01.09
760-4596	06433359001	CD56 (MRQ-42) Rabbit Monoclonal Antibody	13.07.01.09
760-2626	05267366001	CD57 (NK-1) Mouse Monoclonal Antibody	13.07.01.09
760-4249	05269091001	CD61 (2f2) Mouse Monoclonal Antibody	13.07.01.09
760-4379	05463483001	CD63 (NK1/C3) Mouse Monoclonal Antibody	13.07.01.09
760-4589	06433162001	CD71 (MRQ-48) Mouse Monoclonal Antibody	13.07.01.09
760-4380	05463491001	CDX-2 (EPR2764Y) Rabbit Monoclonal Antibody	13.07.01.09
760-4594	06433316001	CEA (CEA31) Mouse Monoclonal Antibody	13.07.01.09
760-2632	05267439001	Collagen Type IV (CIV22) Mouse Monoclonal Antibody	13.07.01.09
760-4254	05269148001	COX-2 (SP21) Rabbit Monoclonal Antibody	13.07.01.09
760-2637	05267471001	Cytokeratin (35betaH11) Mouse Monoclonal Antibody	13.07.01.09
760-4935	07292821001	Cytokeratin 5 (SP27) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4251	05269113001	Cytokeratin 14 (LL002) Mouse Monoclonal Antibody	13.07.01.09
760-4805	06732429001	anti-Cytokeratin 14 (SP53) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4281	05269440001	Cytokeratin 19 (A53-B/A2.26) Mouse Monoclonal Antibody	13.07.01.09
760-4939	07292864001	Cytokeratin 5/14 (EP1601Y/LL002) Rabbit and Mouse Monoclonal Primary Antibody	13.07.01.09
760-4344	05269776001	Cytokeratin 8 & 18 (B22.1 & B23.1) Mouse Monoclonal Antibody	13.07.01.09
760-5060	07709447001	Desmoglein 3 (5G11) Mouse Monoclonal Primary Antibody	13.07.01.09
760-4590	06433189001	DOG1 (SP31) Rabbit Monoclonal Antibody	13.07.01.09
760-4440	05973872001	E-Cadherin (EP700Y) Rabbit Monoclonal Antibody	13.07.01.09
760-4383	05435676001	Ep-CAM/Epithelial Specific Antigen (Ber-EP4) Mouse Monoclonal Antibody	13.07.01.09
760-2640	05267501001	Epstein-Barr Virus (CS1-4) Mouse Monoclonal Antibody	13.07.01.09
760-2642	05267528001	Factor VIII-R Ag. Rabbit Polyclonal Antibody	13.07.01.09
760-4384	05435692001	Factor XIIIa (AC-1A1) Mouse Monoclonal Antibody	13.07.01.09
760-4441	05922470001	Factor XIIIa (EP3372) Rabbit Monoclonal Antibody	13.07.01.09
760-2702	05268117001	Fascin (55k-2) Mouse Monoclonal Antibody	13.07.01.09
760-4937	07292848001	FOXA1 (2F83) Mouse Monoclonal Primary Antibody	13.07.01.09
760-4611	06548938001	anti-FoxP1 (SP133) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-2710	05268192001	FSH Rabbit Polyclonal Antibody	13.07.01.09
760-4256	05269164001	Galectin-3 (9C4) Mouse Monoclonal Antibody	13.07.01.09
760-2643	05267536001	Gastrin Rabbit Polyclonal Antibody	13.07.01.09
760-4897	07107749001	GATA3 (L50-823) Mouse Monoclonal Primary Antibody	13.07.01.09
760-4386	05463530001	GCDPF-15 (EP1582Y) Rabbit Monoclonal Antibody	13.07.01.09
760-4345	05269784001	Glial Fibrillary Acidic Protein (EP672Y) Rabbit Monoclonal Antibody	13.07.01.09
760-2804	05268257001	GH (Growth Hormone) Rabbit Polyclonal Antibody	13.07.01.09
760-2644	05267544001	Glucagon Rabbit Polyclonal Antibody	13.07.01.09
760-4526	06419178001	GLUT1 Rabbit Polyclonal Antibody	13.07.01.09
760-4898	07107757001	Glutamine Synthetase (GS-6) Mouse Monoclonal Primary Antibody	13.07.01.09

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760-4257	05269172001	Glycophorin A (GA-R2) Mouse Monoclonal Antibody	13.07.01.09
760-4442	05973864001	Glypican-3 (1G12) Mouse Monoclonal Antibody	13.07.01.09
760-4283	05269466001	Granzyme B Rabbit Polyclonal Antibody	13.07.01.09
760-2650	05267617001	hCG Rabbit Polyclonal Antibody	13.07.01.09
760-4936	07292830001	Hemoglobin A (SP212) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4350	05269792001	Hepatocyte Specific Antigen (OCH1E5) Mouse Monoclonal Antibody	13.07.01.09
760-4597	06433375001	HGAL (MRQ-49) Mouse Monoclonal Antibody	13.07.01.09
760-4260	05269229001	HHV-8 (13B10) Mouse Monoclonal Antibody	13.07.01.09
760-4261	05269237001	Herpes Simplex Virus I Rabbit Polyclonal Antibody	13.07.01.09
760-4869	07047746001	Herpes Simplex Virus I (10A3) Mouse Monoclonal Primary Antibody	13.07.01.09
760-4262	05269245001	Herpes Simplex Virus II Rabbit Polyclonal Antibody	13.07.01.09
760-4443	05973830001	Human Placental Lactogen (hPL) Rabbit Polyclonal Antibody	13.07.01.09
760-2652	05267625001	IgA Rabbit Polyclonal Antibody	13.07.01.09
760-4444	05973821001	IgD Rabbit Polyclonal Antibody	13.07.01.09
760-2653	05267633001	IgG Rabbit Polyclonal Antibody	13.07.01.09
760-4614	06523854001	anti-IgG4 (MRQ-44) Mouse Monoclonal Primary Antibody	13.07.01.09
760-2654	05267641001	IgM Rabbit Polyclonal Antibody	13.07.01.09
760-6081	08313474001	Inhibin, alpha (MRQ-63) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-2834	05268311001	Inhibin, alpha (R1) Mouse Monoclonal Antibody	13.07.01.09
760-4615	06523862001	anti-INI-1 (MRQ-27) Mouse Monoclonal Primary Antibody	13.07.01.09
760-2655	05267650001	Insulin Guinea Pig Polyclonal Antibody	13.07.01.09
760-4387	05463548001	Ksp-Cadherin (MRQ-33) Mouse Monoclonal Antibody	13.07.01.09
760-2802	05268222001	LH Rabbit Polyclonal Antibody	13.07.01.09
760-4704	06586546001	anti-LMO2 (SP51) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-2656	05267668001	Lysozyme Rabbit Polyclonal Antibody	13.07.01.09
760-2657	05267676001	Macrophage (HAM-56) Mouse Monoclonal Antibody	13.07.01.09
760-4263	05269253001	Mammaglobin (31A5) Rabbit Monoclonal Antibody	13.07.01.09
760-4527	06419186001	Melanoma Associated Antigen (KBA.62) Mouse Monoclonal Antibody	13.07.01.09
760-4528	06419194001	Melanoma Associated Antigen (PNL2) Mouse Monoclonal Antibody	13.07.01.09
760-4445	05973813001	Mesothelial Cell (HBME-1) Mouse Monoclonal Antibody	13.07.01.09
760-4265	05269270001	MSH2 (G219-1129) Mouse Monoclonal Antibody	13.07.01.09
760-4388	05463556001	MUC2 (MRQ-18) Mouse Monoclonal Antibody	13.07.01.09
760-4389	05463564001	MUC5AC (MRQ-19) Mouse Monoclonal Antibody	13.07.01.09
760-4390	05463572001	MUC6 (MRQ-20) Mouse Monoclonal Antibody	13.07.01.09
760-6082	08313482001	MUM1 (EP190) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4529	06419208001	MUM1 (MRQ-43) Rabbit Monoclonal Antibody	13.07.01.09
760-2659	05267692001	Myeloperoxidase Rabbit Polyclonal Antibody	13.07.01.09
760-4900	07107773001	MyoD1 (EP212) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-2832	05268290001	Myogenin (F5D) Mouse Monoclonal Antibody	13.07.01.09
760-2660	05267706001	Myoglobin Rabbit Polyclonal Antibody	13.07.01.09

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760-2704	05268133001	Myosin, Smooth Muscle (SMMS-1) Mouse Monoclonal Antibody	13.07.01.09
760-4867	07047720001	Napsin A (MRQ-60) Mouse Monoclonal Primary Antibody	13.07.01.09
760-4446	05973805001	Napsin A Rabbit Polyclonal Antibody	13.07.01.09
760-4391	05463599001	NGFR (Nerve Growth Factor Receptor) (MRQ-21) Mouse Monoclonal Antibody	13.07.01.09
760-2661	05267714001	Neurofilament (2F11) Mouse Monoclonal Antibody	13.07.01.09
760-4953	07391455001	Neutrophil Elastase (SP203) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-5086	07859759001	NKX3.1 (EP356) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4786	06648568001	anti-NSE (MRQ-55) Mouse Monoclonal Primary Antibody	13.07.01.09
760-4447	05973791001	Oct-2 (MRQ-2) Mouse Monoclonal Antibody	13.07.01.09
760-4392	05463602001	Oct-4 (MRQ-10) Mouse Monoclonal Antibody	13.07.01.09
760-5050	07667973001	Olig2 (EP112) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4453	05973961001	p21/WAF1 (DCS-60.2) Mouse Monoclonal Antibody	13.07.01.09
760-4268	05269300001	p27/Kip1 (SX53G8) Mouse Monoclonal Antibody	13.07.01.09
760-4617	06523897001	anti-p57/Kip2 (Kp10) Mouse Monoclonal Primary Antibody	13.07.01.09
760-4532	06419224001	Parathyroid Hormone (PTH) (MRQ-31) Mouse Monoclonal Antibody	13.07.01.09
760-6077	08313431001	PAX-8 (EP331) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4618	06523927001	anti-PAX-8 (MRQ-50) Mouse Monoclonal Primary Antibody	13.07.01.09
760-4895	07099029001	PD-1 (NAT105) Mouse Monoclonal Antibody	13.07.01.09
760-4394	05463637001	Perforin (MRQ-23) Mouse Monoclonal Antibody	13.07.01.09
760-4434	05973953001	PGP 9.5 Rabbit Polyclonal Antibody	13.07.01.09
760-4591	06433405001	Phosphohistone H3 Rabbit Polyclonal Antibody	13.07.01.09
760-2664	05267757001	PLAP (NB10) Mouse Monoclonal Antibody	13.07.01.09
760-4531	06419216001	PMS2 (EPR3947) Rabbit Monoclonal Antibody	13.07.01.09
760-2665	05267765001	Pneumocystis jiroveci (carinii) (3F6) Mouse Monoclonal Antibody	13.07.01.09
760-4395	05463645001	Podoplanin (D2-40) Mouse Monoclonal Antibody	13.07.01.09
760-2803	05268249001	Prolactin Rabbit Polyclonal Antibody	13.07.01.09
760-4272	05269342001	PSAP (PASE/4LJ) Mouse Monoclonal Antibody	13.07.01.09
760-6076	08313423001	PSMA (EP192) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4273	05269369001	Renal Cell Carcinoma (PN-15) Mouse Monoclonal Antibody	13.07.01.09
760-4620	06523935001	anti-S100P (16/f5) Mouse Monoclonal Primary Antibody	13.07.01.09
760-4864	07047690001	SALL4 (6E3) Mouse Monoclonal Primary Antibody	13.07.01.09
760-6075	08313415001	SATB2 (EP281) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4592	06433278001	Smoothelin (R4A) Mouse Monoclonal Antibody	13.07.01.09
760-2667	05267781001	Somatostatin Rabbit Polyclonal Antibody	13.07.01.09
760-4621	06523943001	anti-SOX-2 (SP76) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4968	07560389001	SOX-10 (SP267) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-4868	07047738001	SOX-11 (MRQ-58) Mouse Monoclonal Primary Antibody	13.07.01.09
760-4274	05269377001	Spectrin (RBC2/3D5) Mouse Monoclonal Antibody	13.07.01.09
760-4449	05973775001	SV40 (MRQ-4) Mouse Monoclonal Antibody	13.07.01.09
760-4595	06433324001	Synaptophysin (MRQ-40) Rabbit Monoclonal Antibody	13.07.01.09
760-4598	06433391001	T-bet (MRQ-46) Rabbit Monoclonal Antibody	13.07.01.09

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760-2669	05267803001	TAG-72 (B72.3) Mouse Monoclonal Antibody	13.07.01.09
760-2670	05267811001	TdT Rabbit Polyclonal Antibody	13.07.01.09
760-4622	06523951001	anti-TFE3 (MRQ-37) Rabbit Monoclonal Primary Antibody	13.07.01.09
760-2671	05267820001	Thyroglobulin (2H11+6E1) Mouse Monoclonal Antibody	13.07.01.09
760-4275	05269385001	TRAcP (9C5) Mouse Monoclonal Antibody	13.07.01.09
760-4276	05269393001	Tryptase (G3) Mouse Monoclonal Antibody	13.07.01.09
760-2709	05268184001	TSH Rabbit Polyclonal Antibody	13.07.01.09
760-4533	06419232001	Uroplakin III (SP73) Rabbit Monoclonal Antibody	13.07.01.09
760-4277	05269407001	Villin (CWWB1) Mouse Monoclonal Antibody	13.07.01.09
760-4397	05435706001	WT1 (6F-H2) Mouse Monoclonal Antibody	13.07.01.09
760-4278	05269415001	ZAP-70 (2F3.2) Mouse Monoclonal Antibody	13.07.01.09