



EC DECLARATION OF CONFORMITY

Manufacturer's Name: ACZON S.P.A
Manufacturer's Address: Via Lavino 265/D
Monte San Pietro (BO)
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Aczon S.p.A. located in Monte San Pietro (Bo) Italy,

DECLARES

under own responsibility, that the products listed on pages 2 to 4 are in conformity with the applicable provisions of Council Directive 98/79/EC of 27 October 1998 regarding the In Vitro Diagnostic Medical Devices.

Therefore the undersigned company grants and declares the following:

- 1) The products listed on pages 2 to 4 fulfil the essential requirements contemplated on the Attachments I of Council Directive 98/79/EC;
- 2) The products listed on pages 2 to 4 are sold in non sterilized packaging
- 3) The products listed on pages 2 to 4 are not measuring instruments

As manufacturer of the mentioned products we declare that we will provide the customs, if required, with the product technical documentation that we will keep stored for a period of 5 years from the product last manufacturing batch.

We therefore declare that the products listed on pages 2 to 4 will be sold as CE marked.

Monte San Pietro 16 November 2006

Aczon SpA
Chief Executive Officer
Ing. Romano Volta



LIST OF EC MARKED IN VITRO DIAGNOSTIC MEDICAL DEVICES

N°	Product Name	Identification Data	EDMA CODE	REF
1	B2M FITC	Mouse monoclonal antibodies for recognizing human cell surface receptors	13-05-01-04-00	ABMGBJ
2	B2M RPE	Mouse monoclonal antibodies for recognizing human cell surface receptors	13-05-01-04-00	ABMG CJ
3	CD1a FITC	Mouse monoclonal antibodies for human lymphocyte subtyping	13-05-01-06-00	A001BJ
4	CD1A RPE	Mouse monoclonal antibodies for human lymphocyte subtyping	13-05-01-06-00	A001CJ
5	CD10 FITC	Mouse monoclonal antibodies for human B and T – cell subtyping	13-05-01-01-00	A010BJ
6	CD10 FITC/CD19 RPE	Mouse monoclonal antibodies identification human cell panels	13-03-04-03-00	B1019J
7	CD10 RPE	Mouse monoclonal antibodies for human B and T – cell subtyping	13-05-01-01-00	A010CJ
8	CD11b FITC	Mouse monoclonal antibodies for recognizing human cell surface receptors	13-05-01-04-00	A11BBJ
9	CD11b RPE	Mouse monoclonal antibodies for recognizing human cell surface receptors	13-05-01-04-00	A11BCJ
10	CD16 FITC	Mouse monoclonal antibodies for human lymphocyte subtyping	13-05-01-06-00	A016BJ
11	CD16 RPE	Mouse monoclonal antibodies for human lymphocyte subtyping	13-05-01-06-00	A016CJ
12	CD19 FITC	Mouse monoclonal antibodies for human B and T – cell subtyping	13-05-01-01-00	A019BJ
13	CD19 RPE	Mouse monoclonal antibodies for human B and T – cell subtyping	13-05-01-01-00	A019CJ
14	CD2 FITC	Mouse monoclonal antibodies for human B and T – cell subtyping	13-05-01-01-00	A002BJ
15	CD2 RPE	Mouse monoclonal antibodies for human B and T – cell subtyping	13-05-01-01-00	A002CJ
16	CD20 FITC	Mouse monoclonal antibodies for human B and T – cell subtyping	13-05-01-01-00	A020BJ
17	CD20 FITC/CD5 RPE	Mouse monoclonal antibodies for human B and T – cell subtyping	13-05-01-01-00	B2005J
18	CD22 FITC	Mouse monoclonal antibodies for human B and T – cell subtyping	13-05-01-01-00	A022BJ
19	CD28 FITC	Mouse monoclonal antibodies for human lymphocyte subtyping	13-05-01-06-00	A028BJ
20	CD28 RPE	Mouse monoclonal antibodies for human lymphocyte subtyping	13-05-01-06-00	A028CJ
21	CD3 FITC	Mouse monoclonal antibodies for human B and T – cell subtyping	13-05-01-01-00	A003BJ
22	CD3 FITC/HLADR RPE	Mouse monoclonal antibodies for human B and T – cell subtyping	13-05-01-01-00	B03DRJ
23	CD3 FITC/CD16+CD56 RPE	Mouse monoclonal antibodies for human lymphocyte subtyping	13-05-01-06-00	B03NKJ
24	CD3 FITC/CD16+CD56 RPE/CD45 PE-CY5	Mouse monoclonal antibodies for human lymphocyte subtyping	13-05-01-06-00	C3N45J
25	CD3 FITC/CD19 RPE	Mouse monoclonal antibodies for human B and T – cell subtyping	13-05-01-01-00	B0319J
26	CD3 FITC/CD19 RPE/CD45 PE-CY5	Mouse monoclonal antibodies for human B and T – cell subtyping	13-05-01-01-00	C31945J
27	CD3 FITC/CD4 RPE	Mouse monoclonal antibodies for human B and T – cell subtyping	13-05-01-01-00	B0304J



N°	Product Name	Identification Data	EDMA CODE	REF
28	CD3 FITC/CD4 RPE/ CD45 PE-CY5	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	C3445J
29	CD3 FITC/CD8 RPE	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	B0308J
30	CD3 FITC/CD8 RPE/ CD45 PE-CY5	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	C3845J
31	CD3 RPE	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	A003CJ
32	CD33 FITC	Mouse monoclonal antibodies for recognizing human cell surface receptors	13-05-01-04-00	A033BJ
33	CD33 RPE	Mouse monoclonal antibodies for recognizing human cell surface receptors	13-05-01-04-00	A033CJ
34	CD38 FITC	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	A038BJ
35	CD38 RPE	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	A038CJ
36	CD4 FITC	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	A004BJ
37	CD4 FITC/CD8 RPE	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	B0408J
38	CD4 FITC/CD8 RPE/CD3 PE-CY5	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	C483J
39	CD4 RPE	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	A004CJ
40	CD41 RPE	Mouse monoclonal antibodies for recognizing human cell surface receptors	13-05-01-04-00	A041CJ
41	CD41 FITC	Mouse monoclonal antibodies for recognizing human cell surface receptors	13-05-01-04-00	A041BJ
42	CD45 FITC	Mouse monoclonal antibodies for recognizing human cell surface receptors	13-05-01-04-00	A045BJ
43	CD45 FITC/CD14 RPE	Mouse monoclonal antibodies identification human cell panels	13-03-04-03-00	B4514J
44	CD45 RPE	Mouse monoclonal antibodies for recognizing human cell surface receptors	13-05-01-04-00	A045CJ
45	CD5 FITC	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	A005BJ
46	CD5 FITC/CD19 RPE	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	B0519J
47	CD5 RPE	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	A005CJ
48	CD61 FITC	Mouse monoclonal antibodies for recognizing human cell surface receptors	13-05-01-04-00	A061BJ
49	CD61 RPE	Mouse monoclonal antibodies for recognizing human cell surface receptors	13-05-01-04-00	A061CJ
50	CD7 FITC	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	A007BJ
51	CD7 RPE	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	A007CJ
52	CD8 FITC	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	A008BJ
53	CD8 FITC/CD56 RPE	Mouse monoclonal antibodies for human lymphocyte subtyping	13-05-01-06-00	B0856J
54	CD8 RPE	Mouse monoclonal antibodies for human B and T - cell subtyping	13-05-01-01-00	A008CJ
55	Control 1 IgG1 FITC	Other monoclonal antibodies	13-05-01-90-00	T001BJ
56	Control 1 IgG1 RPE	Other monoclonal antibodies	13-05-01-90-00	T001CJ



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57	Control 1 IgG2a FITC	Other monoclonal antibodies	13-05-01-90-00	T002BJ
58	Control 1 IgG2a RPE	Other monoclonal antibodies	13-05-01-90-00	T002CJ
59	Control 1 IgG2b FITC	Other monoclonal antibodies	13-05-01-90-00	T003BJ
60	Control 1 IgG2b RPE	Other monoclonal antibodies	13-05-01-90-00	T003CJ
61	Control 2 IgG1 FITC/ IgG1 RPE	Other monoclonal antibodies	13-05-01-90-00	TG011FJ
62	Control 2 IgG1 FITC/ IgG2a RPE	Other monoclonal antibodies	13-05-01-90-00	TG012FJ
63	Control 2 IgG1 FITC/ IgG2b RPE	Other monoclonal antibodies	13-05-01-90-00	TG013FJ
64	Control 2 IgG2a FITC/ IgG1 RPE	Other monoclonal antibodies	13-05-01-90-00	TG021FJ
65	Control 2 IgG2a FITC/ IgG2a RPE	Other monoclonal antibodies	13-05-01-90-00	TG022FJ
66	Control 3 IgG1 FITC/ IgG1 RPE/IgG1 PE-CY5	Other monoclonal antibodies	13-05-01-90-00	TG111GJ
67	Control 3 IgG1 FITC/ IgG2a RPE/IgG1 PE-CY5	Other monoclonal antibodies	13-05-01-90-00	TG121GJ
68	DILUTION BUFFER	Buffer (unassignable), supplm. reagents, etc.	15-90-90-01-00	RDILFX
69	HLA DR FITC	Mouse monoclonal antibodies for human HLA class II determinants	13-05-01-02-00	AHDRBJ
70	HLA DR RPE	Mouse monoclonal antibodies for human HLA class II determinants	13-05-01-02-00	AHDRCJ



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