



# DENKA SEIKEN CO., LTD.

2-1-1, NIHONBASHI-MUROMACHI, CHUO-KU, TOKYO, JAPAN 103-8338

PHONE NUMBER: +81-3-6214-3236 FAX NUMBER: +81-3-6214-3246

## EC Declaration of Conformity

With regard to In Vitro Medical Devices (98/79/EC).

According to Annex III of the IVDD

Manufacturer: **DENKA SEIKEN CO., LTD.**  
2-1-1, Nihonbashi, Muromachi Chuoku, Tokyo, Japan

Products Annex I

Declares under our sole responsibility that the products above fulfill the essential requirements of the EC Council Directive 98/79/EC, and are in accordance with Annex III of the IVDD. All supporting documentation is retained on the premises of the manufacturer.

The following standards were applied:

**ISO 9001: 2008**

**ISO 13485: 2003**

Denka Seiken (hereafter the COMPANY) agrees to develop, implement and maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

The COMPANY confirms that no medicinal products/drugs are incorporated in any device covered by the Device Schedule.

The COMPANY has appointed DENKA SEIKEN UK Limited, as our EU Authorised Representative at the following address:

Unit 12, Business Innovation Centre,  
Binley Business Park, Harry Weston Road,  
Coventry, UK

Signature:

Name:

Nobuyuki YAMADA

Title:

General Manager, Quality Management Dept.

Date:

July 30 2012

Signed on behalf of Denka Seiken Co., Ltd.

## ANNEX I

*Bacterial Products*

Product Code	Description	Size
230782	MRSA-Screen	50 tests
270016	Staphylococcal Coagulase As set	5mLX8
270023	Hemolytic Strept. B-T typing As	2mLX6
270030	Campylobacter As set	2mLX26
270047	Alkaescens-Dispar As set	2mLX5
270054	Streptococcus pneumoniae As set	2mLX47
270061	Staphylococcal Coagulase As I	5mL
270078	Staphylococcal Coagulase As II	5mL
270085	Staphylococcal Coagulase As III	5mL
270092	Staphylococcal Coagulase As IV	5mL
270108	Staphylococcal Coagulase As V	5mL
270115	Staphylococcal Coagulase As VI	5mL
270122	Staphylococcal Coagulase As VII	5mL
270139	Staphylococcal Coagulase As VIII	5mL
270146	Group-B Strept. As I a	2mL
270153	Group-B Strept. As I b	2mL
270160	Group-B Strept. As II	2mL
270177	Group-B Strept. As III	2mL
270184	Group-B Strept. As IV	2mL
270191	Group-B Strept. As V	2mL
270207	Group-B Streptococcus As NT6	2mL
270214	Group-B Streptococcus As JM9	2mL
270221	Group-B Streptococcus As 7271	2mL
270238	Campylobacter As Gp A	2mL
270245	Campylobacter As Gp B	2mL
270252	Campylobacter As Gp C	2mL
270269	Campylobacter As Gp D	2mL
270276	Campylobacter As Gp E	2mL
270283	Campylobacter As Gp F	2mL
270290	Campylobacter As Gp G	2mL
270306	Campylobacter As Gp I	2mL
270313	Campylobacter As Gp J	2mL
270320	Campylobacter As Gp K	2mL
270337	Campylobacter As Gp L	2mL
270344	Campylobacter As Gp N	2mL
270351	Campylobacter As Gp O	2mL
270368	Campylobacter As Gp P	2mL
270375	Campylobacter As Gp R	2mL

## ANNEX I

270382	Campylobacter As Gp S	2mL
270399	Campylobacter As Gp U	2mL
270405	Campylobacter As Gp V	2mL
270412	Campylobacter As Gp Y	2mL
270429	Campylobacter As Gp Z	2mL
270436	Campylobacter As Gp Z2	2mL
270443	Campylobacter As Gp Z4	2mL
270450	Campylobacter As Gp Z5	2mL
270467	Campylobacter As Gp Z6	2mL
270474	Campylobacter As Gp Z7	2mL
270481	Campylobacter Reference As	2mL
270498	Alkalescens-Dispar As poly OK	2mL
270504	Alkalescens-Dispar As O1:K1	2mL
270511	Alkalescens-Dispar As O2:K1	2mL
270528	Alkalescens-Dispar As O3:K2	2mL
270535	Alkalescens-Dispar As O4:K3	2mL
270542	Streptococcus pneumoniae Poly 1 As	2mL
270559	Streptococcus pneumoniae Poly 2 As	2mL
270566	Streptococcus pneumoniae Poly 3 As	2mL
270573	Streptococcus pneumoniae Poly 4 As	2mL
270580	Streptococcus pneumoniae Poly 5 As	2mL
270597	Streptococcus pneumoniae Poly 6 As	2mL
270603	Streptococcus pneumoniae Poly 7 As	2mL
270610	Streptococcus pneumoniae Poly 8 As	2mL
270627	Streptococcus pneumoniae type 1 As	2mL
270634	Streptococcus pneumoniae type 2 As	2mL
270641	Streptococcus pneumoniae type 3 As	2mL
270658	Streptococcus pneumoniae type 4 As	2mL
270665	Streptococcus pneumoniae type 5 As	2mL
270672	Streptococcus pneumoniae type 6 As	2mL
270689	Streptococcus pneumoniae type 7 As	2mL
270696	Streptococcus pneumoniae type 8 As	2mL
270702	Streptococcus pneumoniae type 9 As	2mL
270719	Streptococcus pneumoniae type 10 As	2mL
270726	Streptococcus pneumoniae type 11 As	2mL
270733	Streptococcus pneumoniae type 12 As	2mL
270740	Streptococcus pneumoniae type 14 As	2mL
270757	Streptococcus pneumoniae type 15 As	2mL
270764	Streptococcus pneumoniae type 16 As	2mL
270771	Streptococcus pneumoniae type 17 As	2mL
270788	Streptococcus pneumoniae type 18 As	2mL
270795	Streptococcus pneumoniae type 19 As	2mL
270801	Streptococcus pneumoniae type 20 As	2mL

## ANNEX I

270818	Streptococcus pneumoniae type 21 As	2mL
270825	Streptococcus pneumoniae type 22 As	2mL
270832	Streptococcus pneumoniae type 23 As	2mL
270849	Streptococcus pneumoniae type 24 As	2mL
270856	Streptococcus pneumoniae type 25 As	2mL
270863	Streptococcus pneumoniae type 27 As	2mL
270870	Streptococcus pneumoniae type 28 As	2mL
270887	Streptococcus pneumoniae type 29 As	2mL
270894	Streptococcus pneumoniae type 31 As	2mL
270900	Streptococcus pneumoniae type 32 As	2mL
270917	Streptococcus pneumoniae type 33 As	2mL
270924	Streptococcus pneumoniae type 34 As	2mL
270931	Streptococcus pneumoniae type 35 As	2mL
270948	Streptococcus pneumoniae type 36 As	2mL
270955	Streptococcus pneumoniae type 38 As	2mL
270962	Streptococcus pneumoniae type 39 As	2mL
270979	Streptococcus pneumoniae type 40 As	2mL
270986	Streptococcus pneumoniae type 41 As	2mL
270993	Streptococcus pneumoniae type 46 As	2mL
271006	Streptococcus pneumoniae type 47 As	2mL
271013	Auxiliary Reagents for H. Streptococcus	5mLX7
271020	Diluent for S. Coagulase	20mL
271037	Normal rabbit serum for S. Coagulase	3mL
271044	Normal rabbit plasma for S. Coagulase	3mL
271051	Sensitized Blood Cells for Campylobacter	50 tests
290458	Salmonella As H-a	2mL
290465	Salmonella As H-b	2mL
290472	Salmonella As H-c	2mL
290489	Salmonella As H-d	2mL
290496	Salmonella As H-e,h	2mL
290502	Salmonella As H-G	2mL
290519	Salmonella As H-i	2mL
290526	Salmonella As H-k	2mL
290533	Salmonella H-L	2mL
290540	Salmonella As H-r	2mL
290557	Salmonella As H-y	2mL
290564	Salmonella As H-e,n	2mL
290571	Salmonella As H-1	2mL
290588	Salmonella As H-v	2mL
290595	Salmonella As H-w	2mL
290601	Salmonella As H-z13	2mL
290618	Salmonella As H-z28	2mL
290625	Salmonella As H-2	2mL

## ANNEX I

290632	Salmonella As H-5	2mL
290649	Salmonella As H-6	2mL
290656	Salmonella As H-7	2mL
290663	Salmonella As H-z6	2mL
290670	Salmonella As H-f	2mL
290687	Salmonella As H-m	2mL
290694	Salmonella As H-p	2mL
290700	Salmonella As H-q	2mL
290717	Salmonella As H-s	2mL
290724	Salmonella As H-t	2mL
290731	Salmonella As H-z23	2mL
290748	Salmonella As H-z24	2mL
290755	Salmonella As H-z32	2mL
290762	Salmonella As H-x	2mL
290779	Salmonella As H-z15	2mL
290786	Salmonella As H-z10	2mL
290793	Salmonell As H-z29	2mL
290809	Salmonella As H-z	2mL
290816	Salmonella As H-z4	2mL
290823	Salmonella As H-u	2mL
292421	Salmonella As H phase 1&2	2mL
292445	Salmonella As H rapid 1	2mL
292452	Salmonella As H rapid 2	2mL
292469	Salmonella As H rapid 3	2mL
292476	Salmonella As poly O (A~S)	2mL
292483	Salmonella As poly O (A~G)	2mL
292490	E.coli As poly II (alternative)	2mL
292506	E.coli As poly III (alternative)	2mL
292513	E.coli As poly IV (alternative)	2mL
292520	Salmonella As H-E(Complex)	2mL
292537	Salmonella As Omnivalent	2mL
293688	Haemophilus influenza As set	2mLX6
293695	Haemophilus influenza As a	2mL
293701	Haemophilus influenza As b	2mL
293718	Haemophilus influenza As c	2mL
293725	Haemophilus influenza As d	2mL
293732	Haemophilus influenza As e	2mL
293749	Haemophilus influenza As f	2mL
293756	Yersinia enterocolitica O-As set	2mLX5
293763	Yersinia enterocolitica As poly O 1,2	2mL
293770	Yersinia enterocoliticaAs poly O 3	2mL
293787	Yersinia enterocoliticaAs poly O 5	2mL
293794	Yersinia enterocoliticaAs poly O 8	2mL

## ANNEX I

293800	<i>Yersinia enterocolitica</i> As poly O 9	2mL
293817	<i>Vibrio cholerae</i> As set	2mLX3
293824	<i>V.cholerae</i> As Inaba	2mL
293831	<i>V.cholerae</i> poly As	2mL
293848	<i>V.cholerae</i> As Ogawa	2mL
293855	<i>Salmonella</i> As set 1	2mLX18
293862	<i>Salmonella</i> As set 2	5mLX17
293879	<i>Salmonella</i> As set 3	5mLX4
293886	<i>Salmonella</i> As set 4	5mLX5
293893	<i>Salmonella</i> As set 5	5mLX7
293909	<i>Salmonella</i> As set 6	5mLX5
293916	<i>Salmonella</i> As set 7	2X3 5X2
293923	<i>Salmonella</i> As H-a	5mL
293930	<i>Salmonella</i> As H-b	5mL
293947	<i>Salmonella</i> As H-c	5mL
293954	<i>Salmonella</i> As H-d	5mL
293961	<i>Salmonella</i> As H-e,h	5mL
293978	<i>Salmonella</i> As H-G	5mL
293985	<i>Salmonella</i> As H-i	5mL
293992	<i>Salmonella</i> As H-k	5mL
294005	<i>Salmonella</i> As H-L	5mL
294012	<i>Salmonella</i> As H-r	5mL
294029	<i>Salmonella</i> As H-y	5mL
294036	<i>Salmonella</i> As H-e,n	5mL
294043	<i>Salmonella</i> As H-1	5mL
294050	<i>Salmonella</i> As H-z	5mL
294067	<i>Salmonella</i> As H-z4	5mL
294074	<i>Salmonella</i> As H-z10	5mL
294081	<i>Salmonella</i> As H-z29	5mL
294098	<i>Salmonella</i> As H-v	5mL
294104	<i>Salmonella</i> As H-w	5mL
294111	<i>Salmonella</i> As H-z13	5mL
294128	<i>Salmonella</i> As H-z28	5mL
294135	<i>Salmonella</i> As H-2	5mL
294142	<i>Salmonella</i> As H-5	5mL
294159	<i>Salmonella</i> As H-6	5mL
294166	<i>Salmonella</i> As H-7	5mL
294173	<i>Salmonella</i> As H-z6	5mL
294180	<i>Salmonella</i> As H-f	5mL
294197	<i>Salmonella</i> As H-m	5mL
294203	<i>Salmonella</i> As H-p	5mL
294210	<i>Salmonella</i> As H-q	5mL
294227	<i>Salmonella</i> As H-s	5mL

## ANNEX I

294234	Salmonella As H-t	5mL
294241	Salmonella As H-u	5mL
294258	Salmonella As H-z23	5mL
294265	Salmonella As H-z24	5mL
294272	Salmonella As H-z32	5mL
294289	Salmonella As H-x	5mL
294296	Salmonella As H-z15	5mL
294302	Salmonella As O 1,3,19	2mL
294319	Salmonella As O 11	2mL
294326	Salmonella As O 13	2mL
294333	Salmonella As O 16	2mL
294340	Salmonella As O-18	2mL
294357	Salmonella As Poly O 1	2mL
294364	Salmonella As O 2	2mL
294371	Salmonella As O-21	2mL
294388	Salmonella As O 3,10	2mL
294395	Salmonella As O-35	2mL
294401	Salmonella As O 4	2mL
294418	Salmonella As O 6,14	2mL
294425	Salmonella As O 7	2mL
294432	Salmonella As O 8	2mL
294449	Salmonella As O 9	2mL
294456	Salmonella As O 9,46	2mL
294463	Salmonella As Poly O	2mL
294470	Salmonella As Vi	2mL
294487	V.cholerae As 0139 "Bengal"	2mL
294494	Listeria As H-A	5mL
294500	Listeria As H-AB	5mL
294517	Listeria As H-C	5mL
294524	Listeria As H-D	5mL
294531	Listeria As O I	2mL
294548	Listeria As O I / II	2mL
294555	Listeria As O IV	2mL
294562	Listeria As O V / VI	2mL
294579	Listeria As O VI	2mL
294586	Listeria As O VII	2mL
294593	Listeria As O VIII	2mL
294609	Listeria As O IX	2mL
294616	Listeria As set	2X8 5X4
294623	Legionella As set	2mLX10
294678	Legionella gormanii As	2mL
294685	Legionella dumoffii As	2mL
294746	Legionella pneumophila As Gp.1	2mL

## ANNEX I

294753	Legionella pneumophila As Gp.2	2mL
294760	Legionella pneumophila As Gp.3	2mL
294777	Legionella pneumophila As Gp.4	2mL
294784	Legionella pneumophila As Gp.5	2mL
294791	Legionella pneumophila As Gp.6	2mL
294807	Legionella bozemanii As	2mL
294814	Legionella micdadei As	2mL
294821	Shigella As set 1	2mLX49
294838	Shigella As set 2	2mLX19
294845	Shigella As set 3	2mLX8
294852	Shigella As dysenteriae 1	2mL
294869	Shigella As dysenteriae 10	2mL
294876	Shigella As dysenteriae 11	2mL
294883	Shigella As dysenteriae 12	2mL
294890	Shigella As dysenteriae poly A1	2mL
294906	Shigella As dysenteriae 2	2mL
294913	Shigella As dysenteriae 3	2mL
294920	Shigella As dysenteriae 4	2mL
294937	Shigella As dysenteriae 5	2mL
294944	Shigella As dysenteriae 6	2mL
294951	Shigella As dysenteriae 7	2mL
294968	Shigella As dysenteriae 8	2mL
294975	Shigella As dysenteriae 9	2mL
294982	Shigella As dysenteriae poly A	2mL
294999	Shigella As flexneri (3)4	2mL
295002	Shigella As flexneri I	2mL
295019	Shigella As flexneri II	2mL
295026	Shigella As flexneri III	2mL
295033	Shigella As flexneri IV	2mL
295040	Shigella As flexneri V	2mL
295057	Shigella As flexneri 6	2mL
295064	Shigella As flexneri VI	2mL
295071	Shigella As flexneri 7(8)	2mL
295088	Shigella As flexneri poly B	2mL
295095	Shigella As boydii 1	2mL
295101	Shigella As boydii 10	2mL
295118	Shigella As boydii 11	2mL
295125	Shigella As boydii 12	2mL
295132	Shigella As boydii 13	2mL
295149	Shigella As boydii 14	2mL
295156	Shigella As boydii 15	2mL
295163	Shigella As boydii 16	2mL
295170	Shigella As boydii 17	2mL

## ANNEX I

295187	Shigella As boydii 18	2mL
295194	Shigella As boydii poly C1	2mL
295200	Shigella As boydii 2	2mL
295217	Shigella As boydii poly C2	2mL
295224	Shigella As boydii 3	2mL
295231	Shigella As boydii poly C3	2mL
295248	Shigella As boydii 4	2mL
295255	Shigella As boydii 5	2mL
295262	Shigella As boydii 6	2mL
295279	Shigella As boydii 7	2mL
295286	Shigella As boydii 8	2mL
295293	Shigella As boydii 9	2mL
295309	Shigella As boydii poly C	2mL
295316	Shigella As sonnei phase I	2mL
295323	Shigella As sonnei phase II	2mL
295330	Shigella As sonnei poly D	2mL
295347	Escherichia coli As set 1	2mLX51
295354	Escherichia coli As set 2	5mLX22
295361	E.coli As H-10	5mL
295378	E.coli As H-11	5mL
295385	E.coli As H-12	5mL
295392	E.coli As H-16	5mL
295408	E.coli As H-18	5mL
295415	E.coli As H-19	5mL
295422	E.coli As H-2	5mL
295439	E.coli As H-20	5mL
295446	E.coli As H-21	5mL
295453	E.coli As H-27	5mL
295460	E.coli As H-28	5mL
295477	E.coli As H-34	5mL
295484	E.coli As H-4	5mL
295491	E.coli As H-40	5mL
295507	E.coli As H-41	5mL
295514	E.coli AS H-42	5mL
295521	E.coli As H-45	5mL
295538	E.coli As H-5	5mL
295545	E.coli As H-51	5mL
295552	E.coli As H-6	5mL
295569	E.coli As H-7	5mL
295576	E.coli As H-9	5mL
295583	E.coli As O 1	2mL
295590	E.coli As O 111	2mL
295606	E.coli As O 112ac	2mL

## ANNEX I

295613	E.coli As O 114	2mL
295620	E.coli As O 115	2mL
295637	E.coli As O 119	2mL
295644	E.coli As O 124	2mL
295651	E.coli As O 125	2mL
295668	E.coli As O 126	2mL
295675	E.coli As O 127a	2mL
295682	E.coli As O 128	2mL
295699	E.coli As O 136	2mL
295705	E.coli As O 142	2mL
295712	E.coli As O 143	2mL
295729	E.coli As O 144	2mL
295736	E.coli As O 146	2mL
295743	E.coli As O 148	2mL
295750	E.coli As O 15	2mL
295767	E.coli As O 151	2mL
295774	E.coli As O 152	2mL
295781	E.coli As O 153	2mL
295798	E.coli As O 157	2mL
295804	E.coli As O 158	2mL
295811	E.coli As O 159	2mL
295828	E.coli As O 164	2mL
295835	E.coli As O 166	2mL
295842	E.coli As O 167	2mL
295859	E.coli As O 168	2mL
295866	E.coli As O 169	2mL
295873	E.coli As O 18	2mL
295880	E.coli As O 20	2mL
295897	E.coli As O 25	2mL
295903	E.coli As O 26	2mL
295910	E.coli As O 27	2mL
295927	E.coli As O 28ac	2mL
295934	E.coli As O 29	2mL
295941	E.coli As O 44	2mL
295958	E.coli As O 55	2mL
295965	E.coli As O 6	2mL
295972	E.coli As O 63	2mL
295989	E.coli As O 78	2mL
295996	E.coli As O 8	2mL
296009	E.coli As O 86a	2mL
296016	Escherichia coli As poly 1	2mL
296023	Escherichia coli As poly 2	2mL
296030	Escherichia coli As poly 3	2mL

## ANNEX I

296047	Escherichia coli As poly 4	2mL
296054	Escherichia coli As poly 5	2mL
296061	Escherichia coli As poly 6	2mL
296078	Escherichia coli As poly 7	2mL
296085	Escherichia coli As poly 8	2mL
296146	Staphylo LA	100 tests

*Virological Products*

Code	Description	Size
370013	RDE(II)	20mL x 5
370020	VZV-FA	30 tests

*POCT*

Code	Description	Size
324757	Quick Navi <sup>TM</sup> -Flu	10 tests