

## CE IVD - DECLARATION OF CONFORMITY

<b>Manufacturer</b>	KARTELL SPA Via delle Industrie, 1 20082 Noviglio (MI) Italia
<b>Reference</b>	<b>Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices</b>
<b>Product category:</b>	<b>In Vitro Diagnostic Medical Devices (IVD)</b>
<b>Description:</b>	<b>In vitro diagnostic medical devices serving as sample containers for in vitro analysis.</b>
<b>Classification:</b>	<b>Class A</b>

### Products:

Item number (product identification code)	Description (item identification description)
2919-03 2919-04 2919-06 2919-12 2919-13	EMBEDDING RINGS – White EMBEDDING RINGS – Blue EMBEDDING RINGS – Yellow EMBEDDING RINGS – Green EMBEDDING RINGS (5– Pink
2925-03 2925-04 2925-06 2925-12 2925-13	EMBEDDING CASSETTES MEGA TYPE – White EMBEDDING CASSETTES MEGA TYPE – Blue EMBEDDING CASSETTES MEGA TYPE – Yellow EMBEDDING CASSETTES MEGA TYPE – Green EMBEDDING CASSETTES MEGA TYPE – Pink
2921-03 2921-04 2921-06 2921-10 2921-12 2921-13	EMBEDDING CASSETTES – White EMBEDDING CASSETTES – Blue EMBEDDING CASSETTES – Yellow EMBEDDING CASSETTES – Red EMBEDDING CASSETTES – Green EMBEDDING CASSETTES – Pink
2922	SYNTHETIC SPONGES FOR HISTOLOGICAL CASSETTES
5550 - 5560	SCREW CAP CONTAINER (not sterile)
597	SPUTUM CONTAINER
936	COULTER® TYPE COUNTER CUP
600 - 2595	FEACES CONTAINER (not sterile)
5621 - 5632	SCREW CAP FEACES CONTAINER (not sterile)
5570	URINE CONTAINER (non sterile)
5640- 5643	URINE CONTAINER (not sterile)
5642	SCREW CAP URINE CONTAINER (not sterile)
5630- 2596	CONTAINER FOR URINE AND BIOLOGICAL SAMPLES (not sterile)
5631-2696	CONTAINER FOR URINE AND BIOLOGICAL SAMPLES (not sterile)
479-480	SQUARE URINE BOTTLE White - Amber
481	URINE TANK
482	URINE BOTTLE
2598	SAMPLE CONTAINER
934	SCINTILLATION VIALS
933	SCINTILLATION VIALS
2923 - 2924	HISTOLOGY - BIOPSY METAL TRAYS

Item number (product identification code)	Description (item identification description)
2580 - 2585	SNAP-ON LID CONTAINER
1500 - 1501	COBAS MIRA® TYPE SEGMENTS
2618	OLLI® TYPE CUVETTE
1937-1940-1938- 1960 81937-81940-81938- 81960	CUVETTE FOR SPECTROPHOTOMETRY
1939-1941-1948- 1961 81939-81941-81948- 81961	UV GRADE CUVETTE
82631 - 2631	AMELUNG® CUVETTE
2940-00 2940-04 2940-06 2940-13	COBAS® TYPE TEST TUBES – Neutral COBAS® TYPE TEST TUBES – Blue COBAS® TYPE TEST TUBES – Yellow COBAS® TYPE TEST TUBES – Red/Orange
0298-00 0298-04 0298-06 0298-12 0298-13	MICRO TEST TUBES, 1,5 ml – Neutral MICRO TEST TUBES, 1,5 ml – Blue MICRO TEST TUBES, 1,5 ml – Yellow MICRO TEST TUBES, 1,5 ml – Green MICRO TEST TUBES, 1,5 ml – Pink
0279-00 0279-04 0279-06 0279-12 0279-13	MICRO TEST TUBE grad 1,5 ml (1000 pcs) – Neutral MICRO TEST TUBE grad 1,5 ml (1000 pcs) – Blue MICRO TEST TUBE grad 1,5 ml (1000 pcs) – Yellow MICRO TEST TUBE grad 1,5 ml (1000 pcs) – Green MICRO TEST TUBE grad 1,5 ml (1000 pcs) – Pink
2602	BOHRINGER ES300/600® TYPE CUPS
2501 - 2502 - 2503- 2508	TECHNICON®, BECKMAN®, KONELAB® TYPE CUPS
2510-2511-2600	CENTRIFICHEM®, TECHNICON®, BECKMAN® TYPE CUPS
88301 - 88310 - 88308 – 88108	DISPOSABLE TEST TUBE
2630	FIBRINTIMER® TYPE CUVETTES
297 - 1298 - 1299	GRADUATED MICRO TEST TUBES FOR SAMPLES
88200	CYLINDRICAL TEST TUBE
88210	CYLINDRICAL TEST TUBE
88205	CYLINDRICAL TEST TUBE
300-301	CONICAL TUBES FOR CENTRIFUGE- AUTOCLAVABLE
302-303-305-306- 307-308	CILINDRICAL TEST TUBES FOR CENTRIFUGE- AUTOCLAVABLE
2300-2302-1387- 1388	CONICAL GRADUATED TUBES FOR CENTRIFUGE- AUTOCLAVABLE
88306 – 88320	DISPOSABLE TEST TUBES
88302	DISPOSABLE TEST TUBES
88307	DISPOSABLE TEST TUBES
88302S	DISPOSABLE TEST TUBES
88317- 88319- 88322- 88323 - 88324 - 88325	DISPOSABLE TUBES, WITH RIM
84000 - 84002 - 84004	GRADUATED CONICAL TEST TUBES (not sterile)
84006-84009-84011- 84014	GRADUATED CONICAL CENTRIFUGE TUBES (not sterile)
5620	TEST TUBES WITH SCREW CAP (not sterile)
5600	TEST TUBES WITH SCREW CAP (not sterile)
88303-03 88303-04 88303-06 88303-10 88303/A	CYLINDRICAL TEST TUBE WITH SCREW CAP PP, 15 ml (1000 pcs) – White CYLINDRICAL TEST TUBE WITH SCREW CAP PP, 15 ml (1000 pcs) – Blue CYLINDRICAL TEST TUBE WITH SCREW CAP PP, 15 ml (1000 pcs) – Yellow CYLINDRICAL TEST TUBE WITH SCREW CAP PP, 15 ml (1000 pcs) – Red CYLINDRICAL TEST TUBE WITH SCREW CAP PP, 15 ml (1000 pcs) – White - customized
1962	CAP FOR CUVETTES

Item number (product identification code)	Description (item identification description)
88305-00	TEST TUBE CAPS (1000 pcs) – Neutral
88305-04	TEST TUBE CAPS (1000 pcs) – Blue
88305-06	TEST TUBE CAPS (1000 pcs) – Yellow
88305-10	TEST TUBE CAPS (1000 pcs) – Red
88305-12	TEST TUBE CAPS (1000 pcs) – Green
88309-00	TEST TUBES CAPS (1000 pcs) – Neutral
88309-04	TEST TUBES CAPS (1000 pcs) – Blue
88309-06	TEST TUBES CAPS (1000 pcs) – Yellow
88309-10	TEST TUBES CAPS (1000 pcs) – Red
88309-12	TEST TUBES CAPS (1000 pcs) – Green
88318 - 8832110	DISPOSABLE TEST TUBES CAPS
2512-2514	SAMPLE CUP STOPPERS
650-651-652-654- 655-656-657-658-659	TEST TUBES CAPS
358, 369, 367, 358SA	PETRI DISHES
00368/A ; 3360	PETRI DISHES
2620, 2621, 2622, 2623	MICROTITRATION PLATES (not sterile)

Kartell S.P.A., Labware Division, registered as a manufacturer of in vitro diagnostic medical devices with its headquarter in via delle Industrie 1, Noviglio (MI), declares under its sole responsibility that:

the above mentioned products comply with the product specifications provided by Regulation (EU) 2017/746 of the European Parliament and of the Council related to the in vitro diagnostic medical devices (IVDR).

the products follow the classification of Regulation (EU) 2017/746 and belong to class A.

the technical documentation related to the products listed in this Declaration of Conformity is available upon request by the Competent Authority and is kept for at least 10 years at the manufacturer's premises.

the devices are manufactured under a certified quality management system compliant with ISO 9001: 2015

#### Applicable harmonized standards:

- EN ISO 14971: 2019: Application of risk management to medical devices.
- EN ISO 18113:2009 part 1: In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)
- EN ISO 15223-1:2021: Medical devices — Symbols to be used with medical device labels.
- EN 62366-1:2015: Application of usability engineering to medical devices

Noviglio 14/06/2022

Signature: Dr. Dario Carlo Fumagalli  
 General Manager

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<b>Product category:</b>	<b>In Vitro Diagnostic Medical Devices (IVD)</b>
<b>Description:</b>	<b>In vitro diagnostic medical devices with the function of evaluating erythrocyte sedimentation.</b>
<b>Classification:</b>	<b>Class A</b>

### Products:

Item number (product identification)	Description (item identification description)
88435-88437	SEDIRATE SYSTEM

Kartell S.P.A., Labware Division, registered as a manufacturer of in vitro diagnostic medical devices with its headquarter in via delle Industrie 1, Noviglio (MI), declares under its sole responsibility that:

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the products follow the classification of the Regulation (EU) 2017/746 and belong to class A.

the technical documentation related to the products listed in this Declaration of Conformity is available upon request by the Competent Authority and is kept for at least 10 years at the manufacturer's premises.

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Firma: Dr. Dario Carlo Fumagalli  
General Manager