Kartell

Revisions:
First issue: 26.05.2022
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Revised on 26-01-2026 to add Kartell SRN: Single Registration Number Eudamed

CE IVD - DECLARATION OF CONFORMITY

Manufacturer — **KARTELL SPA**
Via delle Industrie, 1
20082 Noviglio (MI)
Italia

SRN (Single Registration Number): IT-MF-000040990

Reference — **Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices**

Product category: — **In Vitro Diagnostic Medical Devices (IVD)**

Description: — **In vitro diagnostic medical devices serving as sample containers for in vitro analysis.**

Classification: — **Class A**

Products:

Item number (product identification code)	Description (item identification description)	Basic UDI-DI
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	803410578DISPANATOM3M
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**	**803410578CASSINCLS5**
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	803410578CASSINCLS5
2922	SYNTHETIC SPONGES FOR HISTOLOGICAL CASSETTES	803410578DISPANATOM3N
5550 - 5560	SCREW CAP CONTAINER (not sterile)	803410578BICHPLAST3K
597	SPUTUM CONTAINER	803410578DISPSALIVA74
936	COULTER® TYPE COUNTER CUP	803410578DISPCAMPTS
600 - 2595	FEACES CONTAINER (not sterile)	803410578DISPFECITP
5621 - 5632	SCREW CAP FEACES CONTAINER (not sterile)	803410578DISPFECITP
5570	URINE CONTAINER (non sterile)	803410578BICHPLAST3K
5640- 5643	URINE CONTAINER (not sterile)	803410578CONTURINAM7
5642	SCREW CAP URINE CONTAINER (not sterile)	803410578CONTURINAM7
5630	CONTAINER FOR URINE AND BIOLOGICAL SAMPLES (not sterile)	803410578BICHPLAST3K

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Item number (product identification code)	Description (item identification description)	Basic UDI-DI
2596		803410578CONTURINAM7
5631 2696	CONTAINER FOR URINE AND BIOLOGICAL SAMPLES (not sterile)	803410578BICHPLAST3K 803410578CONTURINAM7
479-480	SQUARE URINE BOTTLE White - Amber	803410578CONTURINAM7
481	URINE TANK	803410578CONTURINAM7
482	URINE BOTTLE	803410578CONTURINAM7
2598	SAMPLE CONTAINER	803410578DISPSALIVA74
934	SCINTILLATION VIALS	803410578DISPCAMPTS
933	SCINTILLATION VIALS	803410578DISPCAMPTS
2923 - 2924	HISTOLOGY - BIOPSY METAL TRAYS	803410578DISPANATOM3N
2580 – 2585	SNAP-ON LID CONTAINER	803410578BICHPLAST3K
1500 - 1501	COBAS MIRA® TYPE SEGMENTS	803410578CUVETTENM
2618	OLLI® TYPE CUVETTE	803410578CUVETTENM
1937-1940-1938-1960 81937-81940-81938-81960	CUVETTE FOR SPECTROPHOTOMETRY	803410578CUVETTENM
1939-1941-1948-1961 81939-81941-81948-81961	UV GRADE CUVETTE	803410578CUVETTENM
82631 - 2631	AMELUNG® CUVETTE	803410578CUVETTENM
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	803410578CUVETTENM
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	803410578MICROPLAST9Z
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	803410578MICROPLAST9Z
2602	BOHRINGER ES300/600® TYPE CUPS	803410578CUVETTENM
2501 - 2502 - 2503- 2508	TECHNICON®, BECKMAN®, KONELAB® TYPE CUPS	803410578CUVETTENM
2510-2511	CENTRIFICHEM®, TECHNICON®, BECKMAN® TYPE CUPS	803410578CUVETTENM
2600	HITACHI TIPE® CUPS	803410578CUVETTENM
88301 - 88310 - 88308 – 88108	DISPOSABLE TEST TUBE	803410578PROVPLASTX2
2630	FIBRINTIMER® TYPE CUVETTES	803410578CUVETTENM
297 1298 1299	GRADUATED MICRO TEST TUBES FOR SAMPLES	803410578MICROPLAST9Z 803410578DISPCAMPTS 803410578MICROPLAST9Z
88200	CYLINDRICAL TEST TUBE	803410578PROVPLASTX2
88210	CYLINDRICAL TEST TUBE	803410578PROVPLASTX2
88205	CYLINDRICAL TEST TUBE	803410578PROVPLASTX2
300-301	CONICAL TUBES FOR CENTRIFUGE- AUTOCLAVABLE	803410578PROVPLASTX2
302-303-305-306-307-308	CILINDRICAL TEST TUBES FOR CENTRIFUGE- AUTOCLAVABLE	803410578PROVPLASTX2
2300-2302-1387-1388	CONICAL GRADUATED TUBES FOR CENTRIFUGE- AUTOCLAVABLE	803410578PROVPLASTX2

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Item number (product identification code)	Description (item identification description)	Basic UDI-DI
88306 – 88320	DISPOSABLE TEST TUBES	803410578PROVPLASTX2
88302	DISPOSABLE TEST TUBES	803410578PROVPLASTX2
88307	DISPOSABLE TEST TUBES	803410578PROVPLASTX2
88302S	DISPOSABLE TEST TUBES	803410578PROVPLASTX2
88317- 88319- 88322- 88323 - 88324 - 88325	DISPOSABLE TUBES, WITH RIM	803410578PROVPLASTX2
84000 - 84002 - 84004	GRADUATED CONICAL TEST TUBES (not sterile)	803410578PROVPLASTX2
84006-84009-84011-84014	GRADUATED CONICAL CENTRIFUGE TUBES (not sterile)	803410578PROVPLASTX2
5620	TEST TUBES WITH SCREW CAP (not sterile)	803410578BICHPLAST3K
5600	TEST TUBES WITH SCREW CAP (not sterile)	803410578PROVPLASTX2
88303-03 88303-04 88303-06 88303-10 88303/A	CYLINDRICAL TEST TUBE WITH SCREW CAP PP, 13 ml (1000 pcs) – White CYLINDRICAL TEST TUBE WITH SCREW CAP PP, 13 ml (1000 pcs) – Blue CYLINDRICAL TEST TUBE WITH SCREW CAP PP, 13 ml (1000 pcs) – Yellow CYLINDRICAL TEST TUBE WITH SCREW CAP PP, 13 ml (1000 pcs) – Red CYLINDRICAL TEST TUBE WITH SCREW CAP PP, 13 ml (1000 pcs) – White - customized	803410578PROVPLASTX2
1962	CAP FOR CUVETTES	803410578PROVACCESSGV
88305-00 88305-04 88305-06 88305-10 88305-12 88309-00 88309-04 88309-06 88309-10 88309-12	TEST TUBE CAPS (1000 pcs) – Neutral TEST TUBE CAPS (1000 pcs) – Blue TEST TUBE CAPS (1000 pcs) – Yellow TEST TUBE CAPS (1000 pcs) – Red TEST TUBE CAPS (1000 pcs) – Green TEST TUBES CAPS (1000 pcs) – Neutral TEST TUBES CAPS (1000 pcs) – Blue TEST TUBES CAPS (1000 pcs) – Yellow TEST TUBES CAPS (1000 pcs) – Red TEST TUBES CAPS (1000 pcs) – Green	803410578PROVACCESSGV
88318 - 8832110	DISPOSABLE TEST TUBES CAPS	803410578PROVPLASTX2
2512-2514	SAMPLE CUP STOPPERS	803410578PROVACCESSGV
650-651-652-654-655-656-657-658-659	TEST TUBES CAPS	803410578PROVACCESSGV
358, 369, 367, 358SA	PETRI DISHES	803410578CAPSPETRIBK
00368/A ; 3360	PETRI DISHES	803410578CAPSPETRIBK
2620, 2621, 2622, 2623	MICROTITRATION PLATES (not sterile)	803410578PIASTRPLASTCA

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.

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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 23/01/2026

Signature: Dr. Dario Carlo Fumagalli

General Manager

Kartell

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Manufacturer KARTELL SPA
Via delle Industrie, 1
20082 Noviglio (MI)
Italia

SRN (Single Registration Number): IT-MF-000040990

Reference Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices

Product category: In Vitro Diagnostic Medical Devices (IVD)

Description: In vitro diagnostic medical devices with the function of evaluating erythrocyte sedimentation.

Classification: Class A

Products:

Item number (product identification)	Description (item identification description)	Basic UDI-DI
88435 88437	SEDIRATE SYSTEM	803410578SEDIRATEVB 803410578SEDIRATEPIPYQ

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

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Noviglio, 23/01/2026
Firma: Dr. Dario Carlo Fumagalli
General Manager