CE IVD – DECLARATION OF CONFOMITY

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

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)
88302	CYLINDRICAL TEST TUBE PS, 16x100 mm (500 pcs)
88303	CYLINDRICAL TEST TUBE WITH SCREW CAP PP, 15 ml (1000 pcs
88325	CONICAL TEST TUBES PP, 16x101 mm (2000 pcs)
2940-00	COBAS® TYPE TEST TUBES (1000 pcs) - neutral
2940-04	COBAS® TYPE TEST TUBES (1000 pcs) – Blue
2940-13	COBAS® TYPE TEST TUBES (1000 pcs) – Red/Orange
5550	PP SCREW CAP CONTAINER, 30 ml, ø 35x38 mm (600 pcs),
5570	URINE CONTAINER, 60 ml (500 pcs)
5640	URINE CONTAINER, 150 ml (500 pcs)
1948	UV SEMI-MICRO CUVETTES PMMA (100 pcs)
1960	4-CLEAR FACES MACRO CUVETTES PS (100 pcs)
1961	UV 4-CLEAR FACES MACRO CUVETTES PMMA (100 pcs)
1962	CAPS FOR CUVETTES (1000 pcs)
2300	GRAD CONICAL TUBE 16x112 mm
2501	TECHNICON® TYPE CUPS, 1,5 ml (1000 pcs)
2502	TECHNICON® TYPE CUPS, 2 ml (1000 pcs)
2510	CENTRIFICHEM® TYPE CUPS (1000 pcs)
2511	CUPS TYPE: TECHNICON®, GENSEAC® (1.000 pcs)
2512	CROSS CUT CAPS (1000 pcs)
2514	PUSH-ON CAPS (1000 pcs)
2580	PS CONTAINER 30 ml SNAP-ON LID ø 34x41 mm (800 pcs)
2596	URINE CONTAINER, 200 ml (500 pcs)
2598	SPUTUM CONTAINER (1000 pcs)
2631	AMELUNG® TYPE CUVETTES (1000 pcs)
1939	UV GRADE STD CUVETTE PMMA (100 pcs)
1941	UV SEMI-MICRO CUVETTES PMMA (100 pcs)
1298	MICRO VITATRON, 0,5 ml (1000 pcs)
933	SCINTILLATION VIALS (1000 pcs)
934	SCINTILLATION VIALS MICRO, 4 ml (2000 pcs)
657	TEST TUBE CAPS, 33 mm (100 pcs)
597	SPUTUM CONTAINER, 55 ml (500 pcs)
302	CYLINDRICAL TEST TUBES PP, 100x12 mm
303	CYLINDRICAL TEST TUBES PP, 101x17 mm

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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

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