# 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 |


Kartell S.p.A. via delle Industrie, 1 - 20082 Noviglio (MI) - t. +39 02 900121 - f. +39 02 9053316 - e-mail: kartell@kartell.it - www.kartell.it
CAP. SOC. 26.900.000 DI € VERS. - REG. IMPR. MILANO 11349160157 - REA CCIAA MILANO 1458067 - COD. FISC. 11349160157 - P.I. IT 11349160157 Società con socio unico

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 31/07/2023**