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)
0263100	AMELUNG® TYPE CUVETTES (1000 pcs)

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
- 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
- EN 62366-1:2015: Application of usability engineering to medical devices

Noviglio 06/03/2023

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