

DECLARATION OF CONFORMITY FOR MATERIALS

Hereby we declare that Nuova Aptaca Srl In Vitro Medical Diagnostic Devices (Directive 98/79/CE) cod. 2120/SG, sterile 150 ml urine containers:

1. During devices manufacturing no materials containing natural rubber, latex, synthetic rubber are used (except for Articles of latex). The statement is formulated on the basis of information and statements provided by the producers of the raw materials used.
2. Devices are produced with materials that do not contain substances submitted to restrictions provided by 10/2001/EU Regulation and respect the global and specific migration limits in accordance with the following conditions:
 - Simulant A (distilled water) -40°C for 10 days
 - Simulant B (acetic acid solution 3% p/v) – 40°C for 10 days
 - Simulant C (Ethyl alcohol solution 10% v/v) - 40°C for 10 days
 - Simulant D1 (ethyl alcohol solution at 50% v/v) - 40°C for 10 days
 - Simulant D2 (Vegetable oil - Try substitute made with 95% ethyl alcohol as indicated by the Italian Ministerial Decree 34 of 21.03.1973) - 40°C for 10 daysThe global migration limit, together with all other specific restrictions which monomers and/or additives present in the material can be exposed to, are respected in the use conditions here above. Notes and/or simulant used for migration tests allow to fix the food or the group of food, admitted to the contact with food. The statement is formulated on the basis of analytical tests made by our qualified Laboratory and information and statements provided by the producers of the raw materials used
3. Devices are produced with materials that satisfy the follow requirements:
 - Directive (UE) 2015/863 (substances use restriction – phthalates, sulphates) and following updates and changes
 - 1272/2008 Regulation (labeling and use of dangerous substances) and following updates and changes
 - 10/2011 Regulation (specific migration limits) and following updates and changes 1895/2005/CE Rule (substances use restriction for food contact) and following updates and changes
 - 2011/65/UE Directive (heavy metals, RoHS) and following updating and changes
 - 1895/2005/UE Regulation (objects intended to come in contact with food) and following updates and changes

The use in an industrial or commercial venue of the material indicated in this statement does not exclude the determination of its compliance with applicable rules of competence as well as the technological suitability for the purpose which it is intended by the user.

Canelli, 16 September 2019


Buono Duilio
Quality and Regulatory Affairs Manager