

DECLARATION OF CONFORMITY FOR MATERIALS AND OBJECTS INTENDED TO COME IN CONTACT WITH FOOD

Hereby we declare that

1. Nuova Aptaca Srl In Vitro Medical Diagnostic Devices (Directive 98/79/CE) and Medical Device (93/42/CE):

Are conform to the following CE community legislation:

- 1935/2004/CE Rule (objects intended to come in contact with food) 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
- 2002/72/CE Directive and following updating and changes (food contact) and following updates and changes
- 2005/84/CE Directive (substances use restriction – phthalates, sulphates) and following updates and changes
- 1272/2008 Regulation (labeling and use of dangerous substances) and following updates and changes
- 2011/65/UE Directive (heavy metals, RoHS) and following updating and changes

Conform to the following Italian legislation:

- 21/03/1973 Ministerial Decree and following updating and changes
- 777/82 DPR and following updating and changes

2. During Devices manufacturing no materials containing natural rubber, latex, synthetic rubber are used (except for Articles of latex)
3. Devices are produced with materials that do not contain substances submitted to restrictions as per the above legislations 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 days

The 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.

This is supported with analytical tests made in accordance with 1935/2004/CE, 2023/2006/CE, 2007/19/CE, 10/2011/CE and following updating and changes and Italian Ministerial Decree n° 34 21 March 1973, where applicable.

Notes and/or simulant used for migration tests, indicated on the previous point of the present declaration, allow to fix the food or the group of food, admitted to the contact with food.

This declaration is issued in conformity with the legislation mentioned here above.

The use of the material, indicated in the present declaration , in industrial or commercial premises does not exclude the control of its conformity to the regulations in force and the control of its technological suitability for the target which it is designed for.

This declaration has a validity starting from the date mentioned here below and will be substituted only if there will be important changes in the material production able to change some requirements essential for the conformity and only if the legislative references mentioned in this declaration will be changed and updated so that a new control for the conformity will be needed.

Canelli, li 04.10.2013


Duccio BEONO
Responsabile Assicurazione Qualità