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R.e.a. Modena 203800 – Cap. Soc. € 50.000,00 i.v.
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DECLARATION OF CONFORMITY OF PRODUCTS INTENDED TO COME IN CONTACT WITH FOODSTUFFS

We hereby declare that the **SKY BLUE PELD** tubes produced by the undersigned MEDIFLY SRL, made in the various sizes as per catalogue sheet 10.1, bearing the specific identification pictogram  in the marking, are made with specific raw materials for use in the food sector and are therefore suitable for the passage and conveyance (at T = 40°C) of aqueous food products, alcohol, acids, for dairy products and for any vegetable oil containing less than 1% of unsaponifiable substance.

These tubes are made using materials (PELD and masterbatch) and production processes that are suitable, controlled and compliant with current regulations. All our items are produced and packaged in a controlled environment in accordance with ISO 14644- 1/2/3:2015 EU-GMP 2008 and UNI EN 17141:2021 and classified ISO 8 for microbiological and particulate contamination.

The hoses are produced by MEDIFLY s.r.l. in compliance with the current reference standards and directives (EC Reg. 1935/2004, EC Reg. 2023/2006, EC Reg. 10/2011, Ministerial Decree 21/03/73, Presidential Decree 777/82 and subsequent updates and amendments).

List of substances subject to specific migration limit:

- Zinc Salt MCA106 (CAS 57-11-4)
- Methyl Acrylate MCA 176 (CAS 96-33-3)
- Copper
- Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate MCA 433 (CAS2082-79-3)

List of dual use substances:

- E433 (CAS 9005-65-6)

The analytical tests to certify suitability for contact with foodstuffs were performed in accordance with EC Regulation 10/2011 and subsequent updates and amendments, under the following test conditions: 10 days of contact at a temperature of 40°C, in contact with simulants B, D1, and D2, assuming that 1 kg of food is placed in contact with 6 dm² of tube.

The results obtained allow us to define the tubes as suitable for:

- Prolonged preservation or storage at room temperature or lower;
- Heating up to 70°C for up to 2 hours;
- Heating up to 100°C for up to 15 minutes;

of all foodstuffs corresponding to simulants B, D1, and D2 in Table II of Regulation (EC) No. EC 10/2011 as amended.

The user, in an industrial or commercial setting, is required to verify the conformity of the pipes with respect to the intended technological use and their intended purpose. Furthermore, during use, he must ensure that the pipes are suitable for direct contact with the specific foods for which they are intended, taking into account the actual conditions of use. Therefore, there is no exemption from testing the articles for the intended purposes and suitability for any process and/or end use you are considering.

It is emphasized that the conformity declared here is strictly limited to **SKY BLUE PELD** pipes, as indicated in the previous points, and cannot be extended to any other article/product intended to be connected to such pipes.



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This declaration is to be considered valid as long as there are no substantial changes to the production process, or to the composition of the raw materials, or legislative updates.

Sole Administrator
Ida Battistelli

Medolla, 28/05/2025

MEDIFLY S.R.L.
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