



DECLARATION OF COMPLIANCE

FOR FOOD-CONTACT ARTICLES TREATED WITH VAPORFUSE SURFACING IN THE POWERFUSE S

under the laws and regulations administered by the U.S. Food and Drug Administration

MANUFACTURER / COMPANY

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Hereby, we declare that our solvent **VaporFuse VF47 Eco Fluid**, used in the VaporFuse Surfacing (VFS) process in the Powerfuse S, was evaluated with respect to its chemical composition according to FDA's 21 C.F.R. for 3D-printed food-contact articles.

Further, we declare that our solvent VaporFuse VF47 Eco Fluid, used in the VaporFuse Surfacing process in the Powerfuse S, should not exceed the legal specific migration limit (SML) from plastic articles put in contact with all types of food according to FDA's 21 C.F.R. § 176.170(c).

Based on the evaluation, food-contact articles treated with VaporFuse VF47 Eco Fluid in the VaporFuse Surfacing process in the Powerfuse S are suitable for repeated-use food-contact articles that may be used to contact all food types for which the polymer is both technically suited and authorized.¹

The specific migration limit (SML) of the VaporFuse VF47 Eco Fluid solvent was investigated on Polyamide 12 based EOS PA 2200 test parts treated with our VaporFuse Surfacing process in the DyeMansion Powerfuse S.^{2,3}

The tests were performed according to the following methods:

✓ FDA 21 C.F.R. § 176.170(c), Table 1: FDA's food types.

✓ FDA 21 C.F.R. § 176.170(c), Table 2: FDA's conditions of use.

The specific migration limit of 60 mg/dm² (FDA 21 C.F.R. § 176.170(c)) was not exceeded for repeated contact after 10 days at 40 °C for aqueous and acidic food (10% ethanol), for alcoholic food (50% ethanol) and for fatty food (olive oil).

Philipp Kramer, Vice President

Felix Ewald, President

¹The evaluation does not include the use of our solvent intended to contact infant food.

²The testing results may change depending on the modification of the current regulations, test methods, post-processing steps, the VaporFuse Surfacing process, the composition and the compliance of the used plastic material. It is the responsibility of the distributor to control the food contact compliance of the used material and to test his final product according to the intended conditions of use.

³The parts were additionally vacuum dried.