



Declaration of Compliance regarding Biocompatibility Tests

Manufacturer	EOS GmbH Electro Optical Systems Robert-Stirling-Ring 1 D-82152 Krailling/München
Date of issue	15 July 2021
Product name	EOS TPU 1301
Product code	200001027
Compliance to regulations	With this declaration we confirm that biocompatibility tests have been performed on test specimen made of EOS TPU 1301. The aforementioned tests represent basic compatibility of the material only. The 3D printed test specimen have passed the following tests: <ul style="list-style-type: none">• Cytotoxicity Testing – Neutral Red (ISO 10993-5:2009)• In vitro Skin Irritation Testing – Human Skin Model (OECD Guideline No. 439)• In vivo Sensitisation Testing – Local Lymph Node Assay (ISO 10993-10:2013; OECD Guideline No. 429) Please note that biocompatibility tests are not routinely done for consecutive product lots.

Process conditions, part design, finishing steps and end use conditions all affect the properties and regulatory status of the end application. Due to variation in methods, conditions and equipment, no warranties or guarantees are made as to the suitability or accuracy of this information for use in any end application. It is the responsibility of the user and/or the manufacturer of medical, pharmaceutical or foodstuff final products to ensure that the product is safe, lawful and technically suitable for the intended use.

Authorized signature

Authorized name

Thomas Taxarani – Regulatory Affairs Specialist

This certificate is issued on 15 July 2021 and is of unlimited duration until further notice.

Version 1.0, issued on July 15, 2021