



3 March 2017

REGULATORY INFORMATION SHEET

DuraForm® ProX PA Powder

A. ISO 10993 Certification

DuraForm ProX PA powder has met the requirements of ISO 10993-5 (Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity) and ISO 10993-10 (Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization) standards. Compliance is based on the testing of a single batch which is considered representative of production.

B. Food Contact Certification

The components of this product are listed in regulations promulgated by the U.S. Food and Drug Administration (FDA), 21CFR §177.1500 "Nylon Resins," as resins that may be safely used to produce articles intended for use in processing, handling and packaging non-alcoholic food. The restrictions apply which are contained in §177.1500(b)(9) applicable to Nylon 12 resins.

The components of this product are also listed in the Plastic Directive of the European Union (EU), No 10/2011 and its amendments implementing the regulation (EC) No 1935/2004 for plastics, as appropriate for use in food contact materials subject to the restrictions of:

- 1) Laurolactame (CAS # 947-04-6) SML=5ppm
- 2) 1,6-hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide) (CAS # 23128-74-7) SML=45ppm

Based on these results, it is expected that similar articles made from these products, under conditions of good manufacturing practice and according to 3D Systems recommendations, will meet the compliance requirements of the cited regulations.

It is the responsibility of our customers to determine that their use of our product(s) is safe, lawful, and technically suitable to their intended applications. Customers should conduct their own testing to ensure that this is the case. Because of possible changes in the law and in regulations, as well as possible changes in our products, we cannot guarantee that the status of this product will remain unchanged. We, therefore, recommend that customers continuing to use this product verify its status no less frequently than two years from the date of this publication.

For additional information about this product, please contact David Sloan, Operations Manager, sloand@3dsystems.com.