



## GENERAL CONFORMITY CERTIFICATION

This General Conformity Certification is being provided pursuant to section 14(a) of the Consumer Product Safety Act as amended, 15 U.S.C. 2063(a), and section 102(a)(1) of the Consumer Product Safety Improvement Act of 2017 for products contained in child-resistant packaging in accordance with the Poison Prevention Packaging Act and implementing regulations. See 16 C.F.R. § 1700.14.

Identification of the product covered by the certificate.	<p>Prograf® (tacrolimus) capsules:</p> <ul style="list-style-type: none"> <li>• 0.5 mg/capsule, 100 capsules per bottle (NDC 0469-0607-73)</li> <li>• 1 mg/capsule, 100 capsules per bottle (NDC 0469-0617-73)</li> <li>• 5 mg/capsule, 100 capsules per bottle (NDC 0469-0657-73)</li> </ul>
Regulation(s), rule(s), ban(s), and/or standard(s) to which this product is being certified:	16 C.F.R. § 1700.14(a)(10)
Identification of the U.S. importer or domestic manufacturer certifying compliance of the product:	<p>Astellas US Technologies, Inc.  1 Astellas Way  Northbrook, IL 60025  Phone number: 224-205-8800</p>
Individual maintaining test records upon which this certification is based:	<p>Astellas US Technologies, Inc.  1 Astellas Way  Northbrook, IL 60025</p> <p>Email: <a href="mailto:medinfo.us@astellas.com">medinfo.us@astellas.com</a>  Phone number: 224-205-8800</p>
Date and place where this product was manufactured:	Each manufactured lot is labeled with the National Drug Code (NDC) number and a unique lot number which are used to identify the date and place of manufacture. For additional information, please email <a href="mailto:medinfo.us@astellas.com">medinfo.us@astellas.com</a> .
Date and place where this product was tested for compliance with the regulation(s), rule(s), ban(s) and/or standard(s) cited above and test report(s) on which certification is based:	<p style="text-align: center;">Ringarvegen 7-9  175 79 Jarfalla  Sweden</p> <p>Report No. EI 06:05, dated June 7, 2006</p>
Third-party laboratory that conducted testing upon which this certification is based:	<p style="text-align: center;"><b>Ergonomi Institutet AB,</b>  Ringarvegen 7-9  175 79 Jarfalla  Sweden  +46 (8) 760-1800</p>
Effective date:	October 1, 2018