

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	Prograf ® (tacrolimus) granules for oral
covered by the certificate.	suspension:
	• 0.2 mg per packet, Contains 50 packets
	(NDC 0469-1230-50)
	 1 mg per packet, Contains 50 packets
	(NDC 0469-1330-50)
Regulation(s), rule(s), ban(s),	16 C.F.R. § 1700.14(a)(10)
and/or standard(s) to which this	
product is being certified:	
Identification of the U.S. importer	Astellas US Technologies, Inc.
or domestic manufacturer	1 Astellas Way
certifying compliance of the	Northbrook, IL 60025
product:	Phone number: 224-205-8800
Individual maintaining test records	Astellas US Technologies
upon which this certification is	1 Astellas Way
based:	Northbrook, IL 60025
	, ,
	Email: medinfo.us@astellas.com
	Phone number: 224-205-8800
Date and place where this product	Each manufactured lot is labeled with the National
was manufactured:	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 medinfo.us@astellas.com
Date and place where this product	citati <u>incamo.as e astenas.com</u>
was tested for compliance with the	1001 Forest Trail
regulation(s), rule(s), ban(s) and/or	Sugar Grove, IL 60554 USA
standard(s) cited above and test	Sugar Grove, 1L 00554 CSA
report(s) on which certification is	Report No. 1371-227, dated January 19, 2016
based:	Report No. 13/1-22/, dated January 19, 2010
	DITNED ACCOCIATES INC
Third-party laboratory that	BITNER ASSOCIATES, INC. 1001 Forest Trail
conducted testing upon which this certification is based:	
certification is based:	Sugar Grove, IL 60554 USA
Effective late	708-738-5598
Effective date:	February 15, 2019