

BUREAU VERITAS
Certification



AMANO ENZYME INC.

2-7, 1-CHOME, NISHIKI, NAKA-KU, NAGOYA-SHI, AICHI, 460-8630, Japan

Multisite certificate. Certified sites are listed in the appendix to this certificate

Bureau Veritas Italia S.p.A. certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 13485:2016

Scope of certification

**DESIGN, DEVELOPMENT, MANUFACTURE OF ENZYMES FOR
IN VITRO DIAGNOSTIC USE.**

Original cycle start date:	12/05/2016
Expiry date of previous cycle:	11/05/2022
Certification / Recertification Audit date:	16/02/2022
Certification / Recertification cycle start date:	04/05/2022
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	11/05/2025
Certificate No. - Version: IT273128- 1	Revision date: 04/05/2022

GIORGIO LANZAFAME - Local Technical Manager

Certification body address:
Bureau Veritas Italia S.p.A., Viale Monza, 347 - 20126 Milano, Italia



Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organization.
To check this certificate validity please refer to the website www.bureauveritas.it

SGQ N° 009A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC mutual Recognition Agreements



Attachment to the Certificate of Conformity
IT273128- 1

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Certified Sites

Site	Address	Scope
SALES HEAD OFFICE	2-7, 1-CHOME, NISHIKI, NAKA-KU, NAGOYA-SHI , AICHI, 460-8630, Japan	SALES.
NAGOYA PLANT	27, HANNO, KUNOTSUBO, KITANAGOYA-SHI , AICHI, 481-8533, Japan	DESIGN AND DEVELOPMENT.
YORO PLANT	3600-1, MAKIDA, KAMIISHIZU-CHO, OGAKI-SHI , GIFU, 503-1602, Japan	MANUFACUTURING, QUALITY CONTROL, QUALITY ASSURANCE.
INOVATION CENTER	6, TECHNOPLAZA 1-CHOME KAKAMIGAHARA-SHI, GIFU, 509-0109, Japan	DEVELOPMENT

Version No. 1

1/2

Revision date: 04/05/2022

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