Lloyd's Register

Certificate of Approval

This is to certify that the Management System of:

Ventana Medical Systems, Inc.

1910 East Innovation Park Drive, Tucson, AZ, 85755, United States

has been approved by LRQA to the following standards:

ISO 13485:2003
EN ISO 13485:2012

SAO Y BẢN CHÍNH
Ngày ..... Tháng ..... Năm .....
M.S.D.N: 0310805269 - C.T.T.N.H.H
CÔNG TY TRÁCH NHIỆM HỮU HẠN ROCHE VIỆT NAM
Q. BÌNH THẠNH - TP. HỒ CHÍ MINH
Rodney James Wa
Tổng Giám Đốc

Chris Koci
Issued By: Lloyd's Register Quality Assurance, Inc. for and on behalf of: Lloyd's Register Quality Assurance Ltd

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current Issue Date: 7 November 2017
Expiry Date: 31 March 2019
Certificate Identity Number: 10037287

Original Approvals:
ISO 13485 7 November 2017

Approval Certificate Number: ISO 13485 – 00011308

The scope of this approval is applicable to:
Design and Development, Manufacture, of Reagents and Instruments for Clinical Histology and Clinical Cytology.

UKAS MANAGEMENT SYSTEMS
001

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Certificate Schedule

Certificate Identity Number: 10037287

Location	Activities
1910 East Innovation Park Drive, Tucson, AZ, 85755, United States	ISO 13485:2003 Design, Development and Manufacture of Reagents and Instruments for Clinical Histology and Clinical Cytology.
9831 West Tangerine Road, Marana, AZ, 85653, United States	ISO 13485:2003 Manufacture and Warehousing.
1915 East Innovation Park Drive, Tucson, AZ, 85755, United States	ISO 13485:2003 Design and Development.

UKAS MANAGEMENT SYSTEMS

001

ISO106

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Sanmina-SCI Systems de Mexico SA de CV
Km 15.5 No. 29, Plant 06
Carr. Chapala-Guadalajara, Jalisco 45640
Mexico

BẢN CHÍNH
Ngày ..... Tháng ..... Năm .....
CÔNG TY TRÁCH NHIỆM HỮU HẠN ROCHE VIỆT NAM
Q. BÌNH THẠNH-TP. HỒ CHÍ MINH
Rodney James Ward
Tổng Giám Đốc

has established and applies a quality management system for medical devices for the following scope:

Contract Manufacturing and Testing of Electromechanical Medical Equipment Subassemblies and Components

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2016-09-01
Certificate Registration No.:	SX 60112285 0001
An audit was performed. Report No.:	31592827 001
This Certificate is valid until:	2019-08-31

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2016-08-05

Jürgen Welte

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