

**CERTIFICATO N.
CERTIFICATE N. 1116.2022**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

Ewell Plastics Co., Ltd
億瑋塑膠股份有限公司

No. 7, Alley 6, Ln. 520, Nanshang Rd., Guishan Dist., Taoyuan City 33392, Taiwan (R.O.C.)
33392桃園市龜山區南上路520巷6弄7號

UNITA' OPERATIVE / OPERATIVE UNITS

No. 7, Alley 6, Ln. 520, Nanshang Rd., Guishan Dist., Taoyuan City 33392, Taiwan (R.O.C.)
33392桃園市龜山區南上路520巷6弄7號

E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Manufacturing of non-sterile plastic components for Medical Disposable I.V. Infusion set.
醫療器材點滴輸液組非滅菌塑膠射出零件之製造.

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	2022-08-30	2025-08-29	2028-08-29



IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

Certificate

CISQ/IMQ has issued an IQNET recognized certificate that the organization:

EWELL PLASTICS CO., LTD

No. 7, Alley 6, Ln. 520, Nanshang Rd., Guishan Dist., Taoyuan City 333392, Taiwan (R.O.C.)

has implemented and maintains a

Quality Management System

for the following scope:

Manufacturing of non-sterile plastic components for Medical Disposable I.V. Infusion set

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **2025/08/29**

Expires on: **2028/08/29**

Registration Number: **IT-138846-1116.2022**


Alex Stoichitoiu
President of IQNET


Mario Romersi
President of CISQ



This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

IQNET Members*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy CQC China CQM China CQS Czech Republic
Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA FCAV Brazil FONDONORMA Venezuela ICONTEC
Colombia ICS Bosnia and Herzegovina INTECO Costa Rica IRAM Argentina JQA Japan KFQ Korea LSQA Uruguay MIRTEC Greece
MSZT Hungary Nemko AS Norway NSAI Ireland NYCE-SIGE México PCBC Poland Quality Austria Austria SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TSE Türkiye YUQS Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com