

**CERTIFICATE N.
CERTIFICADO N. 1353.2023**

WE HEREBY CERTIFY THAT THE ENVIRONMENTAL MANAGEMENT SYSTEM OPERATED BY
CERTIFICA QUE EL SISTEMA DE GESTIÓN MEDIOAMBIENTAL DE

STE PHARMACEUTICALS S.L.U.

AVDA UNIVERSITAT AUTÓNOMA 13 PARC TEC. DEL VALLÈS -
08290 CERDANYOLA DEL VALLÉS (BARCELONA) SPAIN

SITI / CENTROS DE

View the Annex for the Sites (n. 2 pages)
Ver el Anexo de los Sitios (n. 2 páginas)

IS IN COMPLIANCE WITH THE STANDARD / REÚNE LOS REQUISITOS DE LA NORMA

ISO 14001:2015

FOR THE FOLLOWING ACTIVITIES / PARA LAS SIGUIENTES ACTIVIDADES

Diseno, fabricacion y ventas: Solucion esteril y no esteril para limpieza de cavidades nasales; Solucion no esteril para limpieza oido externo; Aspirador nasal manual para bebes; Solucion no esteril para la garganta; Dispositivos medicos en forma liquida para el tratamiento de la tos. Elaboracion de complementos alimenticios en forma liquida. Dosificacion y envasado de estas formas liquidas en viales bebibles y frascos nebulizadores. Envasado en blister de los complementos alimenticios en forma solida. Fabricacion de inyectables y formas solidas orales (citostaticas y alta potencia)

Design, manufacture and sales: Sterile solution and non-sterile for the cleaning of nasal cavities; Non sterile solution for external otic cleaning; Nasal aspirators for babies; Non sterile solutions for throat; Medical devices in liquid form to treat coughs; Manufacturing of liquid food supplements. Dosification and packaging of these liquid food supplements in vials and nebulizer bottles. Packaging in blister of solid food supplements. Manufacturing of injectable and solid oral forms (cytostatic and high potency)

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS
EL PRESENTE CERTIFICADO ESTÁ SUJETO AL RESPETO DEL REGLAMENTO
PARA LA CERTIFICACIÓN DE LOS SISTEMAS DE GESTIÓN

DATE:	FIRST CERTIFICATION PRIMERA CERTIFICACIÓN	CURRENT ISSUE EMISION ACTUAL	EXPIRY VÁLIDO HASTA
	2023-12-06	2024-06-06	2026-12-05



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

ANNEX N. **1353.2023-1**
ANNEXO N°

STE PHARMACEUTICALS S.L.U.

CTRA. DE VALLS TV-2034 KM. 6 – 43886 VILABELLA (TARRAGONA) SPAIN

Activities:
Actividades:

Diseño, fabricación y ventas: Solución estéril y no estéril para limpieza de cavidades nasales; Solución no estéril para limpieza oído externo; Aspirador nasal manual para bebés; Solución no estéril para la garganta; Dispositivos médicos en forma líquida para el tratamiento de la tos. Elaboración de complementos alimenticios en forma líquida. Dosificación y envasado de estas formas líquidas en viales bebibles y frascos nebulizadores.

Envasado en blíster de los complementos alimenticios en forma sólida.

Design, manufacture and sales: Sterile solution and non-sterile for the cleaning of nasal cavities; Non sterile solution for external otic cleaning; Nasal aspirators for babies; Non sterile solutions for throat; Medical devices in liquid form to treat coughs; Manufacturing of liquid food supplements. Dosification and packaging of these liquid food supplements in vials and nebulizer bottles. Packaging in blister of solid food supplements

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO: STE PHARMACEUTICALS S.L.U.
EL OBJETIVO DEL ANEXO ES EXPLICAR LAS ACTIVIDADES REALIZADAS EN CADA SEDE / UNIDAD OPERATIVA DE LA CERTIFICACIÓN DEL SISTEMA DE GESTIÓN EMITIDA A: STE PHARMACEUTICALS S.L.U.

FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE NR. 1353.2023
PARA LA FECHA DE CADUCIDAD, VER EL CERTIFICADO NR. 1353.2023

DATES:	FIRST CERTIFICATION PRIMERA CERTIFICACIÓN	CURRENT ISSUE EMISION ACTUAL	EXPIRY VÁLIDO HASTA
	2023-12-06	2024-06-06	2026-12-05



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



MS N° 0005MS

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

Il presente documento integra il certificato n. 1353.2023
This document is part of certificate n. 1353.2023

IAF: 13

The validity of the certificate is submitted to annual audit and a reassessment
of the entire management System within three years
La validez del certificado está sujeta a auditorías anuales y a la recertificación
completa del Sistema de Gestión con una periodicidad trienal.



www.cisq.com

CISQ è la Federazione Italiana di Organismi di
Certificazione dei sistemi di gestione aziendale. CISQ
is the Italian Federation of management system
Certification Bodies.

ANNEX N. 1353.2023-2
ANNEXO N°

PRASFARMA, S.L.U.

C/ SANT JOAN 11 – 15 – 08560 MANLLEU (BARCELONA) SPAIN

Activities:
Actividades:

Fabricación de inyectables y formas sólidas orales (citostáticas y alta potencia)
Manufacturing of injectable and solid oral forms (cytostatic and high potency)

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT
OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO: STE PHARMACEUTICALS S.L.U.
EL OBJETIVO DEL ANEXO ES EXPLICAR LAS ACTIVIDADES REALIZADAS EN CADA SEDE / UNIDAD OPERATIVA
DE LA CERTIFICACIÓN DEL SISTEMA DE GESTIÓN EMITIDA A: STE PHARMACEUTICALS S.L.U.

FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE NR. 1353.2023
PARA LA FECHA DE CADUCIDAD, VER EL CERTIFICADO NR. 1353.2023

DATES:	FIRST CERTIFICATION PRIMERA CERTIFICACIÓN 2023-12-06	CURRENT ISSUE EMISION ACTUAL 2024-06-06	EXPIRY VÁLIDO HASTA 2026-12-05
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IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
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is the Italian Federation of management system
Certification Bodies.

Certificate

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

STE PHARMACEUTICALS S.L.U.

CTRA. DE VALLS TV-2034 KM. 6 – 43886 VILABELLA (TARRAGONA) SPAIN

PRASFARMA, S.L.U.

C/ SANT JOAN 11 – 15 – 08560 MANLLEU (BARCELONA) SPAIN

has implemented and maintains a
Environmental Management System

for the following scope:

**Design, manufacture and sales: Sterile solution and non-sterile for the cleaning of nasal cavities;
Non sterile solution for external otic cleaning; Nasal aspirators for babies; Non sterile solutions for throat;
Medical devices in liquid form to treat coughs; Manufacturing of liquid food supplements. Dosification and
packaging of these liquid food supplements in vials and nebulizer bottles. Packaging in blister of solid food
supplements. Manufacturing of injectable and solid oral forms (cytostatic and high potency)**

which fulfils the requirements of the following standard:

ISO 14001:2015

Issued on: **2024/06/06**

Expires on: **2026/12/05**

Registration Number: **IT-140010-1353.2023**


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.

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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
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