

CERTIFICATO n°
CERTIFICATE n° **18697**

SI CERTIFICA CHE L'ORGANIZZAZIONE
WE HEREBY CERTIFY THAT THE ORGANIZATION

LABOMAR SPA

IT-31036 ISTRANA (TV) - VIA N. SAURO 35/I

NELLE SEGUENTI UNITA' OPERATIVE / IN THE FOLLOWING OPERATIVE UNITS

IT - 31036 ISTRANA (TV) - VIA N. SAURO 35/D
IT - 31036 ISTRANA (TV) - VIA BRIGATA MARCHE, 1 C
IT - 31036 ISTRANA (TV) - VIA FILZI 33
IT - 31036 ISTRANA (TV) - VIA FILZI, 55
IT - 31036 ISTRANA (TV) - VIA N. SAURO 35/I

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE QUALITA' CHE E' CONFORME ALLA NORMA
HAS IMPLEMENTED AND MAINTAINS A QUALITY MANAGEMENT SYSTEM WHICH COMPLIES WITH THE FOLLOWING STANDARD

UNI CEI EN ISO 13485:2016

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

Progettazione, Produzione e Confezionamento, anche conto terzi, di Dispositivi Medici a base di sostanze: * per il trattamento dei disturbi della mucosa nasale e orofaringea, nella forma di compresse, liquidi, gel, * per il trattamento dei disturbi gastrointestinali, nella forma di compresse, polveri, liquidi, gel, * per il trattamento dei disturbi della mucosa vaginale, nella forma di capsule, liquidi, gel, creme, * per il trattamento dei disturbi della cute e delle ferite superficiali, nella forma di liquidi, gel, emulsioni. Progettazione e gestione della produzione, anche conto terzi, di Dispositivi Medici a base di sostanze: * per il trattamento dei disturbi della mucosa nasale nella forma di liquidi nebulizzabili sterili in ripartizione asettica, * per il trattamento dei disturbi della mucosa ano-rettale, nella forma di gel, supposte, * per il trattamento dei disturbi della superficie ungueale, nella forma di liquidi.

*Design, Production and Packaging, also on behalf of third parties, of Medical Devices based on substances: * for the treatment of disorders of the nasal and oropharyngeal mucosa, in the form of tablets, liquids, gels, * for the treatment of gastrointestinal disorders, in the form of tablets, powders, liquids, gels, * for the treatment of disorders of the vaginal mucosa, in the form of capsules, liquids, gels, creams, * for the treatment of skin disorders and superficial wounds, in the form of liquids, gels, emulsions. Design and production management, also on behalf of third parties, of substance-based medical devices: * for the treatment of nasal mucosal disorders in the form of sterile nebulizable liquids in aseptic distribution, * for the treatment of disorders of the anorectal mucosa, in the form of gels, suppositories, * for the treatment of nail surface disorders, in the form of liquids.*

IL PRESENTE CERTIFICATO È 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 THE CERTIFICATION OF MANAGEMENT SYSTEMS

PRIMA EMISSIONE FIRST ISSUE	07/01/2013
DATA DELIBERA DECISION DATE	03/01/2022
DATA SCADENZA EXPIRY DATE	02/01/2025
EMISSIONE CORRENTE CURRENT ISSUE	03/01/2022



SGQ n. 008 A

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

CERTIQUALITY S.r.l. IL PRESIDENTE
Via G. Giardino 4 - 20123 MILANO (MI) - ITALY



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.



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/CERTIQUALITY S.r.l.

has issued an IQNet recognised certificate that the organization:

LABOMAR SPA

IT-31036 ISTRANA (TV) - VIA N. SAURO 35/I

for the following scope

*Design, Production and Packaging, also on behalf of third parties, of Medical Devices based on substances: * for the treatment of disorders of the nasal and oropharyngeal mucosa, in the form of tablets, liquids, gels, * for the treatment of gastrointestinal disorders, in the form of tablets, powders, liquids, gels, * for the treatment of disorders of the vaginal mucosa, in the form of capsules, liquids, gels, creams, * for the treatment of skin disorders and superficial wounds, in the form of liquids, gels, emulsions. Design and production management, also on behalf of third parties, of substance-based medical devices: * for the treatment of nasal mucosal disorders in the form of sterile nebulizable liquids in aseptic distribution, * for the treatment of disorders of the anorectal mucosa, in the form of gels, suppositories, * for the treatment of nail surface disorders, in the form of liquids.*

has implemented and maintains a
Quality Management System
which fulfills the requirements of the following standard
ISO 13485:2016

Issued on: 03/01/2022
First issued on: 07/01/2013
Expires on: 02/01/2025

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

Registration number: **IT- 77548**

Cisq Certificate: **18697**



Alex Stoichitoiu
President of IQNET



Ing. Mario Romersi
President of CISQ

IQNet Partners*:

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 Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland NYCE-
SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

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