

CERTIFICATO n° **18697**
CERTIFICATE n°

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
IT - 31036 ISTRANA (TV) - VIA MONTE SANTO, 6/A
IT - 31036 ISTRANA (TV) - VIA S. GIOVANNI BOSCO, 22/A

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

UNI CEI EN ISO 13485:2021

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

VEDASI ALLEGATO/SEE ANNEX

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 09/12/2024

DATA SCADENZA
EXPIRY DATE 02/01/2028

EMISSIONE CORRENTE
CURRENT ISSUE 09/12/2024



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

IL PRESENTE CERTIFICATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO ALLEGATO
THIS CERTIFICATE IS NOT VALID WITHOUT THE RELEVANT ANNEX



SGQ n. 008 A

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



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.

ALLEGATO AL CERTIFICATO n°
ANNEX TO CERTIFICATE n°

18697

For information concerning the validity of the certificate, you can visit the site www.certiquality.it

The validity of this certificate depends on annual audit and on a complete review every three years of the Management System.

LABOMAR SPA

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

Progettazione e produzione , anche conto terzi, ed immissione in commercio di Dispositivi Medici a base di sostanze:
per il trattamento dei disturbi della mucosa nasale e orofaringea, nella forma di compresse, liquidi e gel;
per il trattamento dei disturbi gastrointestinali, nella forma di compresse, polveri, liquidi e gel, esclusi i dispositivi medici che incorporano tessuti di origine animale;
per il trattamento dei disturbi della mucosa vaginale, nella forma di capsule, liquidi, gel e creme;
per il trattamento dei disturbi della cute e delle ferite superficiali, nella forma di liquidi, gel ed emulsioni.
Progettazione e gestione della produzione, anche conto terzi, ed immissione in commercio di Dispositivi Medici a base di sostanze:
per il trattamento dei disturbi della mucosa ano-rettale, nella forma di gel e supposte;
per il trattamento dei disturbi della superficie ungueale, nella forma di liquidi.

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| PRIMA EMISSIONE FIRST ISSUE | 07/01/2013 |
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*Design and production , also on behalf of third parties, and placing on the market 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, excluding medical devices incorporating tissue origin
animal;
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, and placing on
the market of substance-based medical devices:
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.*

For information concerning the validity
of the certificate, you can visit the site
www.certiquality.it

The validity of this certificate depends
on annual audit and on a complete
review every three years of the
Management System.

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Certificate

CISQ/CERTIQUALITY S.r.l. has issued an IQNET recognized certificate that the organization:

LABOMAR SPA

IT-31036 ISTRANA (TV) - VIA N. SAURO 35/1

has implemented and maintains a/an

Quality Management System

for the following scope:

Design and production , also on behalf of third parties, and placing on the market 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, excluding medical devices incorporating tissue origin animal;

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, and placing on the market of substance-based medical devices:

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.

which fulfils the requirements of the following **standard:**

ISO 13485:2016

Issued on: 09/12/2024

First issued on: 07/01/2013

Expires on: 02/01/2028

Registration Number: **IT- 77548 - 18697**



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*:

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