

CERTIFICATO n°
CERTIFICATE n° **16338**

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

BIOFARMA S.R.L.

IT - 33036 MERETO DI TOMBA (UD) - VIA CASTELLIERE 2

NELLE SEGUENTI UNITA' OPERATIVE / IN THE FOLLOWING OPERATIVE UNITS

IT - 33036 MERETO DI TOMBA (UD) - VIA DIVISIONE JULIA, 23

IT - 33036 MERETO DI TOMBA (UD) - VIA CASTELLIERE, 2

IT - 33036 MERETO DI TOMBA (UD) - VIA DIVISIONE JULIA, 25

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 13485:2021

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

Ricerca e sviluppo, produzione, anche conto terzi, e immissione in commercio di dispositivi medici a base di sostanze per uso topico (liquidi, gel, creme, unguenti e forme solide), uso orale (solidi e liquidi) e uso dentale (liquidi).

Ricerca e sviluppo, gestione della produzione e immissione in commercio di dispositivi medici sterili impiantabili per viscosupplementazione.

Research and development, production and packaging, both as manufacturers and third party producers, of medical devices based on substances for topical use (liquids, gels, creams, ointments and solid forms), oral use (solids and liquids) and dental use (liquids).

Research and development, production and packaging management, release of visco-supplementary implantable sterile medical devices.

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 13/01/2011

DATA DELIBERA
DECISION DATE 20/12/2024

DATA SCADENZA
EXPIRY DATE 03/12/2025

EMISSIONE CORRENTE
CURRENT ISSUE 20/12/2024



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



SGQ n. 008 A

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



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

Certificate

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

BIOFARMA S.R.L.

IT-33036 MERETO DI TOMBA (UD) - VIA CASTELLIERE 2

has implemented and maintains a/an
Quality Management System

for the following scope:

**Research and development, production and packaging, both as manufacturers and third party producers, of medical devices based on substances for topical use (liquids, gels, creams, ointments and solid forms), oral use (solids and liquids) and dental use (liquids).
Research and development, production and packaging management, release of visco-supplementary implantable sterile medical devices.**

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

ISO 13485:2016

Issued on: 20/12/2024
First issued on: 13/01/2011
Expires on: 03/12/2025

Registration Number: **IT- 57291 - 16338**


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**
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LSQA Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria**
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