

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). Produzione e immissione in commercio di dispositivi medici a base di sostanze per uso dentale (liquidi). Ricerca e sviluppo, gestione della produzione e immissione in commercio di dispositivi medici sterili impiantabili per viscosupplementazione.

Research and development, manufacturing, including for third parties, and placing on the market of substance-based medical devices for topical use (liquids, gels, creams, ointments, and solid forms) and oral use (solids and liquids).

Manufacturing and placing on the market of substance-based medical devices for dental use (liquids).

Research and development, production management, and placing on the market of sterile implantable medical devices for viscosupplementation.

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 24/11/2025

DATA SCADENZA
EXPIRY DATE 02/12/2028

EMISSIONE CORRENTE
CURRENT ISSUE 24/11/2025



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



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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.

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, manufacturing, including for third parties, and placing on the market of substance-based medical devices for topical use (liquids, gels, creams, ointments, and solid forms) and oral use (solids and liquids). Manufacturing and placing on the market of substance-based medical devices for dental use (liquids).

Research and development, production management, and placing on the market of sterile implantable medical devices for viscosupplementation.

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

ISO 13485:2016

Issued on: 24/11/2025
First issued on: 13/01/2011
Expires on: 02/12/2028

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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Colombia **ICS** Bosnia and Herzegovina **Inspecta Sertifointi Oy** Finland **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**
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