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CERTIFICATO N.  
CERTIFICATE No.

ICIM-13485-050733-01

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI  
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

**BIOGYN SRL**

UNITÀ OPERATIVA / OPERATIVE UNIT

VIA A. VOLTA, 14 41037 MIRANDOLA MO IT - Italia

È CONFORME ALLA NORMA

**UNI CEI EN ISO 13485:2021**

IS IN COMPLIANCE WITH THE STANDARD

**ISO 13485:2016**

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

Progettazione, produzione e immissione in commercio di dispositivi medici monouso per: iniezione, infusione, irrigazione, dermatologia, dialisi, ginecologia e accessori. Assemblaggio e confezionamento di dispositivi medici monouso su specifica del cliente. Commercializzazione di dispositivi medici per ginecologia.

*Design, production and marketing of disposable medical devices and related accessories for: injection, infusion, irrigation, dermatology, dialysis, gynecology. Assembly and packaging of disposable medical devices on customer specifications. Marketing of medical devices for gynecology.*

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.  
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.  
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.

For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

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Vincenzo Delacqua  
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MS N° 0004



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/ICIM S.P.A.** has issued an IQNET recognized certificate that the organization:

## **BIOGYN SRL**

**VIA A. VOLTA, 14 41037 MIRANDOLA MO IT - Italia**

has implemented and maintains a/an

### **Quality Management System**

for the following scope:

**Design, production and marketing of disposable medical devices and related accessories for: injection, infusion, irrigation, dermatology, dialysis, gynecology . Assembly and packaging of disposable medical devices on customer specifications. Marketing of medical devices for gynecology.**

which fulfils the requirements of the following standard:

## **ISO 13485:2016**

Issued on: **2024-05-19**

First issued on: **2018-08-31**

Expires on: **2027-05-18**

Registration Number:

**IT-149732 ICIM-13485-050733-01**



**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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