

**CERTIFICATO N.
CERTIFICATE N. 0415.2024**

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

BIOSERVICE TUNISIE

ZONE INDUSTRIELLE ENFIDHA - 4030 ENFIDHA TUNISIE

UNITA' OPERATIVE / OPERATIVE UNITS

ZONE INDUSTRIELLE ENFIDHA - 4030 ENFIDHA TUNISIE

E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Fabricación, stérilisation et commercialisation de dispositifs médicaux à usage unique stérile:
poches de drainage, système de mesure de diurèse horaire, tubulure d'aspiration, kit pour
paracentèse et thoracentèse, set pour lavage urologique et irrigation arthroscopie, kit et
canule d'aspiration chirurgicale, perfuseur, transfuseur et ligne d'extension
*Manufacturing, sterilization and marketing of medical devices for sterile single-use:
drainage bags, system for measuring hourly diuresis, tubes for surgical aspiration,
kit for paracentesis and thoracentesis, set for urology wash and arthroscopy irrigation,
kit and cannula for surgical aspiration, infusor, transfusor and extension line*

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' 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 CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION 2023-06-27	EMISSIONE CORRENTE CURRENT ISSUE 2024-04-19	SCADENZA EXPIRY 2026-08-30
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Management Systems Division - Flavio Ornago

La data di prima certificazione è riferita al rilascio da parte di altro organismo
First certification date is related to issue date of another Certification Body