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CERTIFICATO N. 1152.2020  
CERTIFICATE N.

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

**PROMEPLA S.A.M.**

9 AVENUE ALBERT II - 98000 MONACO MONACO  
UNITA' OPERATIVE / OPERATIVE UNITS

9 AVENUE ALBERT II - 98000 MONACO MONACO

**PROMEDTECH**

ZI M-GHIRA 2 BEN AROUS - 2082 FOUCHENA TUNISIA

**EMOTECHNIC SARL**

PARC D'ACTIVITE OUKACHA - HANGAR 1 - AIN SEBAA CASABLANCA MOROCCO

**ROCAMED FRANCE**

ZI DE SIGNES ALLÉE DE STOCKHOLM - 83870 SIGNES FRANCE

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

**ISO 13485:2016**

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Fabrication et commercialisation de composants a usage medical, de dispositifs medicaux implantables / non implantables, steriles / non steriles, a usage unique / reutilisables.

Fabrication, commercialisation et SAV de dispositifs médicaux d'irrigation / d'aspiration pour la chirurgie endoscopique et tubulures associees. Negoce de dispositifs medicaux

Manufacturing and sales of components for medical use, implantable / no implantable medical devices, sterile / no sterile for single use / reusable. Manufacturing, sales and after sale services of irrigation/suction medical devices for endoscopic surgery and associated pipes. Trading of medical devices

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	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	2018-07-19	2020-07-31	2021-07-20

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY  
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



SGQ N° 005 A

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

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale  
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years



Organismo di Certificazione Federato CISQ  
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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.