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CERTIFICATO N.  
CERTIFICATE N. 1152.2020

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

Vedere gli Allegati per le Unità Operative (n° 3 pagine)  
View the Annexes for the Operative Units (n° 3 pages)

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

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Conception, fabrication et mise sur le marché de composants à usage médical, de dispositifs médicaux implantable / non-implantables, stériles / non-stériles, à usage unique / réutilisables. Management de la conception, fabrication et SAV de dispositifs médicaux d'irrigation/d'aspiration pour la chirurgie endoscopique et tubulures associées.

Négoce et commercialisation de composants à usage médical.

Design, manufacturing and placing on the market of components for medical use, implantable / non implantable medical devices, sterile / non-sterile for single use / reusable. Design management, manufacturing and after-sales of irrigation/suction medical devices for endoscopic surgery and associated pipes. Trading and sales of components for medical use

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 2018-07-19	EMISSIONE CORRENTE CURRENT ISSUE 2021-07-12	SCADENZA EXPIRY 2024-07-20
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IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY  
Management Systems Division - Flavio Ornago



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



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ALLEGATO N. 1152.2020-1  
ANNEX N.

## PROMEPLA S.A.M.

9 AVENUE ALBERT II - 98000 MONACO MONACO

Attività:  
Activities:

Conception de composants à usage médical, de dispositifs médicaux implantable / non-implantables, stériles / non-stériles, à usage unique / réutilisables. Management de la conception, de dispositifs médicaux d'irrigation/d'aspiration pour la chirurgie endoscopique et tubulures associées.  
*Design of components for medical use, implantable / non-implantable medical devices, sterile / non-sterile, for single use / reusable. Design management of irrigation/suction medical devices for endoscopic surgery and associated pipes*

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A PROMEPLA S.A.M.

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO PROMEPLA S.A.M.

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 1152.2020  
FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE N. 1152.2020

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	2018-07-19	2021-07-12	2024-07-20

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ALLEGATO N. 1152.2020-2  
ANNEX N.

## PROMEPLA S.A.M.

ZI DE SIGNES ALLÉE DE STOCKHOLM - 83870 SIGNES FRANCE

Attività:  
Activities:

Processus support pour la conception et fabrication de composants à usage médical, de dispositifs médicaux implantable / non-implantables, stériles / non-stériles, à usage unique / réutilisables. Management de la conception, fabrication et SAV de dispositifs médicaux d'irrigation/d'aspiration pour la chirurgie endoscopique et tubulures associées.  
*Support processes for design and manufacturing of components for medical use, implantable / non-implantable medical devices, sterile / non-sterile, for single use / reusable.*  
*Design management, manufacturing and after-sales of irrigation/suction medical devices for endoscopic surgery and associated pipes.*

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A PROMEPLA S.A.M.

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ALLEGATO N. 1152.2020-3  
ANNEX N.

## PROMEPLA S.A.M.

PROMEDTECH ZI M-GHIRA 2 BEN AROUS - 2082 FOUCHENA TUNISIA

EMOTECHNIC SARL PARC D'ACTIVITÉ OUKACHA - HANGAR 1 - AIN SEBAA  
CASABLANCA MOROCCO

Attività:  
Activities:

Fabrication de composants à usage médical, de dispositifs médicaux implantable / non-implantables, stériles / non-stériles, à usage unique / réutilisables. Fabrication et SAV de dispositifs médicaux d'irrigation/d'aspiration pour la chirurgie endoscopique et tubulures associées.  
Manufacturing of components for medical use, implantable / non-implantable medical devices, sterile / non-sterile, for single use / reusable. Manufacturing and after-sales of irrigation/suction medical devices for endoscopic surgery and associated pipes.

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO  
IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE  
DEL SISTEMA DI GESTIONE RILASCIATA A PROMEPLA S.A.M.

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OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO PROMEPLA S.A.M.

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