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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	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	2018-07-19	2021-07-12	2024-07-20

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



SGQ N° 005 A



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