

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 26053 rev. 2

Le LNE certifie que le système de management de la qualité développé par
LNE certifies that the quality management system developed by

PROMEPLA S.A.M.
9 avenue Albert II
98000 MONACO

pour les activités
for the activities

Conception et fabrication de tubulure d'irrigation/aspiration stériles à usage unique

Design and manufacturing of sterile single use pipes for irrigation/suction

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485 : 2016

Début de validité / Effective date July 19th, 2018 (included)
Valable jusqu'au / Expiry date : December 31st, 2018 (included)
Etabli le / Issued on : July 19th, 2018



On behalf of the G-MED Certification Director
Béatrice LYS
G-MED Certification Technical Director



LNE N° 26053-2
LNE: CMDCAS recognized registrar / This certificate is issued according to the rules of G-MED certification and CMDCAS program requirements
Renouvelle le certificat 26053-1

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

French version :

Conception et fabrication de tubulure d'irrigation/aspiration stériles à usage unique.

English version :

Design and manufacturing of sterile single use pipes for irrigation/suction.

PROMEPLA S.A.M. - 9 avenue Albert II - 98000 MONACO - MONACO

Siège social – Conception / Headquarters - Design

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

Fabrication / Manufacturing

EMOTECHNIC SARL - Parc d'activité Oukacha - Hangar 1 - Ain Sebaa - CASABLANCA - MAROC

Fabrication / Manufacturing

ROCAMED FRANCE - ZI de Signes - Allée de Stockholm - 83870 SIGNES – France

Activités de stockage, de distribution et d'injection / Activities of storage, of distribution and of injection

4 sites / 4 sites



On behalf of the G-MED Certification Director
Béatrice LYS
G-MED Certification Technical Director