Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	PROMEPLA S.A.M.
Manufacturer address and contact details	9 avenue Albert II 98000 Monaco Monaco
Single Registration Number (SRN) (if available)	MC-MF-000015769

Authorised Representative name (if applicable)	Promepla Group S.à r.l.
Authorised Representative address and contact details	44 Avenue J-F Kennedy 1855 Luxembourg Luxembourg
Single Registration Number (SRN) (if available)	LU-AR-00013458

Notified body name (if applicable)	☑See attached schedule
Notified body number (if applicable)	☑See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☑See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☑See attached schedule
End date of extended validity/transition period	☑See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Le Copori • 9, avenue Albert II • MC 98000 MONACO

Société Anonyme Monégasque au capital de 588.420 €
S.S.E.E. 4669 B0 1526 • R.C.I. 69 S 1239
N° individuel d'identification FR29000009059

PROMEPLA

Tel. +377 97 98 42 32
e-mail: contact@promepla.com
www.promepla.com

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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☐ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☑ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

PROMEPLA S.A.M.

Done in Monaco on May, 10th 2024

Béatrice DOMINGUEZ, Head of Regulatory Affairs

bd@promepla.com

PROMEPLA S.A.M.
9 AVENUE ALBERT II
98000 MONACO
MONACO

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
PDF102	10061	May 26th, 2024	GMED (0459)	IMQ (0051)	December 31st, 2028	/

[1] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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ATTESTATION / *CERTIFICATE* **N° 10061 rev. 11**
Délivrée à Paris le 23 septembre 2019
Issued in Paris on September 23rd, 2019

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système d'assurance Qualité de la Production/ *Approval of Production Quality Assurance System*
ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices
Pour les dispositifs de classe IIb ou III, un certificat CE de type est requis
For class IIb or III devices, a EC type certificate is required

Fabricant / *Manufacturer*

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

Catégorie du(des) dispositif(s) / *Device(s) category*

Dispositifs médicaux pour l'Odontologie, l'Endoscopie, la Gynécologie, l'Ophtalmologie, la Perfusion, la Transfusion et la Dialyse.
Dispositifs médicaux stériles ou non stériles, à usage unique ou réutilisables, non-implantables.

Medical devices for Dentistry, Endoscopy, Gynecology, Ophatlmology, Perfusion, Transfusion and Dialysis.
Sterile or not sterile, single use or reusable, not implantable medical devices.

Voir détails sur addendum
See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P177340-1 / P600719, le système d'assurance qualité - pour la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P177340-1 / P600719, the quality system - for manufacturing and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex V section 3.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **September 23rd, 2019 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

GMED_b5-F-V0-07-2018

GMED - 10061 rev. 11
Renouvelle le certificat 10061-10

GMED
GROUPE LNE

Addendum au certificat n° 10061 rev. 11 **page 1/1**
Addendum of the certificate n° 10061 rev. 11
Dossier(s) / *File(s)* N° P177340-1 & P600719

Identification des dispositifs / *Identification of devices*

Les produits couverts par ce certificat sont référencés sur la liste des produits attachée à la Déclaration CE de conformité du 22 aout 2019 (10 pages) et authentifiée par GMED le 29 aout 2019 / *The products covered by this certificate are listed on the manufacturer's list of products attached to the CE Declaration of conformity of August 22nd, 2019 (10 pages) and authenticated by GMED on August 29th, 2019.*

Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites:

PROMEPLA S.A.M. – 9 avenue Albert II – MC 98000 – 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*

GMED	0459

GMED SAS GMED SAS

On behalf of the President
Béatrice LYS
Technical Director