UNISURGE

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*
- 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	**Unisurge International Ltd**
Manufacturer address and contact details	Farboud Innovation Park, Formula Drive, Newmarket, Suffolk CB8 0BF
Single Registration Number (SRN) (if available)	GB-PR-000033353

Authorised Representative name (if applicable)	CMC Medical Devices& Drugs
Authorised Representative address and contact details	CMC Medical Devices& Drugs C/Horacio Lengo N18 CP29006 malaga Spain info@cmcmedicaldevices.com +34951214054
Single Registration Number (SRN) (if available)	ES-AR-000000293

Notified body name (if applicable)	GMED □ See attached schedule
Notified body number (if applicable)	0459 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	36899 rev 3 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	11th September 2023 □ See attached schedule
End date of extended validity/transition period	31st December 2027 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate**, the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- 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Certificate(s) covering the listed device(s) was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.

- Our MDD certificate expires *after* 20 March 2023:
  - Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made already and also submitted by us to a notified body well ahead of the 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- Quality Management System (QMS)
  A QMS in accordance with Article 10(9) MDR is in place.
  Please note that the MDR Article 10 (9) complaint Quality management system has already been implemented by Unisurge International Limited.

- Applicable device(s) are as per listed in the attached schedule. We declare that:
  - 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:

UNISURGE INTERNATIONAL LIMITED

Farboud Innovation Park

Formula Drive

Newmarket

Suffolk

CB8 0BF

Julie Shaftoe

8.08.2023

UNISURGE
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RA Manager

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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)
F1 Family - ANAESTHETIC PROCEDURE PACKS	36899	11/09/2023	GMED SAS	GMED SAS	31st December 2027	**N/A**
F2 Family - CARDIO Thoracic PROCEDURE PACKS	36899	11/09/2023	GMED SAS	GMED SAS	31st December 2027	**N/A**
F3 Family - GENERAL PROCEDURE PACKS	36899	11/09/2023	GMED SAS	GMED SAS	31st December 2027	**N/A**
F4 Family - F4 Neurosurgery PROCEDURE PACKS	36899	11/09/2023	GMED SAS	GMED SAS	31st December 2027	**N/A**
F5 Family - F5 OPHTHALMIC PROCEDURE PACKS	36899	11/09/2023	GMED SAS	GMED SAS	31st December 2027	**N/A**
F6 Family - F6 ORTHOPAEDIC PROCEDURE PACKS	36899	11/09/2023	GMED SAS	GMED SAS	31st December 2027	**N/A**
F7 Family - F7 PLASTIC PROCEDURE PACKS	36899	11/09/2023	GMED SAS	GMED SAS	31st December 2027	**N/A**
F8/F9 Families - F8/F9 essentials and Supplementary PROCEDURE PACKS	36899	11/09/2023	GMED SAS	GMED SAS	31st December 2027	

See Attached GMED MDD Certificate no 36899 rev 3 including scope:

"Sterile single use procedure packs- Single-use war dressing packs- sterile single-use supplementary surgical packs: surgical drapes, gowns, single use surgical instruments"

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