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

- 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	Copan Italia S.p.A.
Manufacturer address and contact details	Via Francesco Perotti, 10 – Brescia 25125, Italy Contact: regulatory.affairs@copangroup.com
Single Registration Number (SRN) (if available)	IT-MF-000022535

Authorised Representative name (if applicable)	Not applicable
Authorised Representative address and contact details	Not applicable
Single Registration Number (SRN) (if available)	Not applicable

Notified body name (if applicable)	TÜV SÜD PRODUCT SERVICE GmbH
Notified body number (if applicable)	0123
Directive Certificate number(s) to which this confirmation is made (if applicable)	G1 073936 0014 Rev. 03

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26th May 2024
End date of extended validity/transition period	31st December 2028

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/or
- 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** as listed above
  Directive Certificate covering the listed device(s) was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.
  Expires after 20 March 2023:
  Formal application to the notified body in accordance with Section 4.3, first subpara-graph of Annex VII MDR for conformity assessment has been made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule and signed written agreement 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.
  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 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:

Brescia, 2024/05/13

Elisabetta Zanella
Chief Regulatory Officer
Copan Italia S.p.A.
Email contact: regulatory.affairs@copangroup.com

Schedule of Devices

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

Identification of the device	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)	BASIC UDI-DI reported in Confirmation Letter Regarding Amending Regulation (EU) 2023/607 CL 073936 0020 Rev. 00
80.1301	G1 073936 0014 Rev. 03	26th May 2024	TÜV SÜD PRODUCT SERVICE GmbH NB number: 0123	TÜV SÜD PRODUCT SERVICE GmbH NB number: 0123	31st December 2028	Not applicable	80533260AD0032AM00169
80.1303	G1 073936 0014 Rev. 03	26th May 2024	TÜV SÜD PRODUCT SERVICE GmbH NB number: 0123	TÜV SÜD PRODUCT SERVICE GmbH NB number: 0123	31st December 2028	Not applicable	80533260AD0032AM00169