

## 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

<u>Manufacturer name</u>	Copan Italia S.p.A.
<u>Manufacturer address and contact details</u>	Via Francesco Perotti, 10 – Brescia 25125, Italy  Contact: regulatory.affairs@copangroup.com
<u>Single Registration Number (SRN) (if available)</u>	IT-PR-000033865

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

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

<u>Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)</u>	26 <sup>th</sup> May 2024
<u>End date of extended validity/transition period</u>	31 <sup>st</sup> 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Certificate covering the listed device(s) was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.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.

- **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](mailto: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 0021 Rev.00
80.1361	G1 073936 0014 Rev. 03	26 <sup>th</sup> May 2024	TÜV SÜD PRODUCT SERVICE GmbH NB number: 0123	TÜV SÜD PRODUCT SERVICE GmbH NB number: 0123	31 <sup>st</sup> December 2028	Not applicable	80533260BD008P2M002GW
80.1363	G1 073936 0014 Rev. 03	26 <sup>th</sup> May 2024	TÜV SÜD PRODUCT SERVICE GmbH NB number: 0123	TÜV SÜD PRODUCT SERVICE GmbH NB number: 0123	31 <sup>st</sup> December 2028	Not applicable	80533260BD008P2M002GW
80.1362	G1 073936 0014 Rev. 03	26 <sup>th</sup> May 2024	TÜV SÜD PRODUCT SERVICE GmbH NB number: 0123	TÜV SÜD PRODUCT SERVICE GmbH NB number: 0123	31 <sup>st</sup> December 2028	Not applicable	80533260BD008P2M002GW
80.1366	G1 073936 0014 Rev. 03	26 <sup>th</sup> May 2024	TÜV SÜD PRODUCT SERVICE GmbH NB number: 0123	TÜV SÜD PRODUCT SERVICE GmbH NB number: 0123	31 <sup>st</sup> December 2028	Not applicable	80533260BD008P2M002GW
80.1366.001	G1 073936 0014 Rev. 03	26 <sup>th</sup> May 2024	TÜV SÜD PRODUCT SERVICE GmbH NB number: 0123	TÜV SÜD PRODUCT SERVICE GmbH NB number: 0123	31 <sup>st</sup> December 2028	Not applicable	80533260BD008P2M002GW