PPWR Declaration of Sutter Medizintechnik GmbH

With reference to Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC (hereinafter referred to as the PPWR), Sutter Medizintechnik GmbH declares the following:

- The primary and sterile packaging has been developed within the Design Control process in accordance with ISO 13485 and ISO 14971. It is compliant with the Medical Device Regulation (MDR) and MDSAP requirements and, as of today, is exempt from the requirements of the PPWR.
- The remaining packaging materials - standard packaging consisting primarily of cardboard and cushioning materials - have been assessed in their entirety. Based on current knowledge, the packaging materials used do not contain PFAS or other regulated substances above the applicable regulatory limits.
- As part of our PPWR project, all packaging materials are being identified, indexed, and assessed. Data sheets and/or declarations of conformity are being obtained, and contracts with suppliers and service providers are being amended where necessary.
- The assessment is based on the current implementation status of Regulation (EU) 2025/40 and the information currently available from our suppliers. Sutter Medizintechnik continuously reviews applicable requirements and updates the relevant documentation and evidence as needed.
- An overview of the status of our PPWR activities - including both implemented and planned measures - is available on our website: EU Packaging and Packaging Waste Regulation (PPWR) – Regulation (EU) 2025/40 - Sutter

Emmendingen, Germany

July 29, 2026

Bert Sutter
CEO