AMDR MEMBER CODE OF CONDUCT

AMDR members must be in the business of reprocessing or remanufacturing devices originally labeled for "single-use," and agree to abide by this Code of Conduct, the AMDR Bylaws, Mission Statement, Credo, and Antitrust Policy.

AMDR Members agree to <u>comply with all laws and regulations, including</u>:

- meeting requirements established by the United States Food and Drug Administration (FDA), European Medical Device Regulation, or applicable requirements in the jurisdiction where the reprocessed device is marketed;
- registering with regulatory agencies and meeting marketing requirements of each country in which its devices are marketed;
- obtaining a premarket clearance (510(k) or approval, CE mark, or equivalent applicable marketing authorization;
- implementing compliance programs to ensure that members' quality systems adhere to FDA or applicable requirements for each country in which its devices are marketed;
- demonstrating to AMDR staff that the member is in substantial compliance with FDA's Quality System Regulation (QSR), ISO 13485 quality system, and/or equivalent standard in the jurisdiction in which it markets devices;
- clearly and consistently marking devices as reprocessed, including the name of the reprocessor;
- testing and inspecting 100% of devices to ensure functionality, performance, and patient safety;
- affirming that marketed devices do not exceeding the maximum number of cycles (turns) for each device as authorized by the regulatory authority, notified body, or indicated by the original manufacturer as safe number of uses; and
- implementing professional standards for operations and management.

AMDR Members agree to <u>support hospital and healthcare provider partners</u> by:

- aligning the reprocessing industry with the interests of hospitals and healthcare providers;
- providing data that demonstrates cost and carbon emission savings from operating reprocessing engagements;
- leveraging and prioritize the supply chain benefits of reprocessed or remanufactured single-use devices to benefit hospitals and healthcare providers;
- engaging in transparent and fair interactions with hospital partners; and
- helping our provider partners to reduce cost, waste, and greenhouse gas emissions, and build supply chain resilience through the use of reprocessed SUDs;

AMDR Members agree to <u>engage in ethical marketing practices</u> by:

- Conducting themselves in an open, transparent and accountable manner with hospital and healthcare providers so they may make informed decisions about medical device utilization;
- Supporting hospitals and healthcare providers in their efforts to maximize the value of existing medical device assets to reduce cost, waste, and greenhouse gas emissions;
- Assisting hospital and healthcare providers in ensuring manufacturer agreements and initiatives do not lessen the carbon emissions or net cost savings results from reprocessing programs;
- Avoiding deceptive or false marketing claims, void of hidden or confusing prices or terms and accountable and transparent in providing reporting on reprocessing figures;
- Avoiding acts or unethical practice in advertising, marketing or business activities in general that would bring discredit to or lack of confidence in the association or industry; and
- Not engaging in agreements, or other arrangements in violation of applicable antitrust laws.

The AMDR Board shall have exclusive authority to determine if a member of the association has violated this Code of Conduct (Board's Powers of Censure, Suspension or Cancellation, outlined in AMDR's Bylaws, Article 5, Section 3).