

# Statement of quality

# INTEGRA

**Product name:** All GRIPTIPS® and CLEAR ADVANTAGE™ reservoirs

## Our commitment to customers:

**INTEGRA** consumables are produced from virgin materials using precise and consistent manufacturing techniques to ensure quality and excellent performance. INTEGRA is committed to advance the use of recycled materials and bio-based plastics in the packaging of its consumables, wherever possible.

Our product lots are traceable down to the corresponding raw material used and date produced. Our manufacturing process incorporates consistent in process inspection throughout all phases of fabrication and assembly. All consumables are produced in a controlled environment to ensure purity and cleanliness. INTEGRA consumables produced under these conditions are contaminant free and consistent from lot to lot.

The following applies:

**Sterility:** Consumables labeled as **sterile** have been packaged under controlled conditions and have additionally been gamma irradiated within the minimum and maximum dosage range specified for GRIPTIPS and CLEAR ADVANTAGE reservoirs:

**Maximum specified dose (kGy) 22.5**

**Minimum specified dose (kGy) 12.5**

Sterile products are considered sterile until opened.

**Pyrogen testing:** VIAPURE labeled products are tested for endotoxins. Technicians certified to USP/FDA guidelines for medical devices perform the Limulus Amoebocyte Lysate (LAL) test according to the USP compendial guidelines <85>. The endotoxin acceptance level is < 0.06 EU/ml.

**Human DNA and PCR inhibition:** Approved lots are free of detectable genomic DNA and are free of PCR inhibiting contaminants.

**TSE/BSE statement:** The resins used in the manufacturing of these products are free of animal-origin ingredients and therefore deemed to be free of TSE/BSE- causing agents.

**Ribonuclease (RNase):** VIAPURE lots are tested for RNase and are free of any detectable degradation of RNA.

**Deoxyribonuclease (DNase):** VIAPURE lots are tested for DNase and are free of any detectable degradation of DNA.

Email: [info@integra-biosciences.com](mailto:info@integra-biosciences.com)

[www.integra-biosciences.com](http://www.integra-biosciences.com)

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