

General Quality Certificate

Green Elephant® CellScrew®



Product Name:	Green Elephant® CellScrew®		6K	10K	mini
Product Number:	GEB-CS6KTCS	GEB-CS10KTCS	GEB-CSmTCS		

Green Elephant Biotech certifies that the product has been manufactured in accordance with established manufacturing guidelines and product specifications. The product meets all Green Elephant Biotech quality requirements.

ISO Certification - Green Elephant Biotech's quality management system is certified according to ISO 9001:2015-09.

Materials - All products are produced with materials such as plant derived polylactic acid. Our materials are confirmed as:

- Animal ingredients free (no risk from BSE)
- Bisphenol A ("BPA") free
- Biocompatibility tested according to ISO 10993-5
- REACH compliant
- RoHS certified
- FDA and EU Title 21 compliant

Production - Products are manufactured in a controlled environment according to Green Elephant Biotech's quality standards.

Functional Testing - Products undergo continuous quality controls regarding function, precision, and reproducibility. Visual checks, testing of weight and pressure testing, etc. are part of Green Elephant Biotech's quality assurance standards.

Sterility - Sterile products are sterilized by gamma irradiation with a dosage range from 25 kGy to 40 kGy.

Biocompatibility Testing - Biological testing procedures ensure that the product is free from endotoxins (<0.0125 EU/ml) and does not have a cytotoxic effect in vitro.

Testing is conducted by an independent, EN ISO/ IEC 17025-accredited laboratory.

Endotoxin is tested according to EN ISO 10993-11 (2018) and Eu.-Phr.2.6.14.

In vitro cytotoxicity is tested according to EN ISO 10993-5 (2009).

Testing is conducted by an independent, EN ISO/ IEC 17025-accredited laboratory.

Traceability - The product is fully traceable by lot number.

Sabrina Seidler
Head of Quality Management