

## SUMMARY TECHNICAL DOCUMENTATION

### GAMMA STERILIZATION

#### ***Sterilization by Gamma Irradiation:***

Waldemar Link GmbH & Co. KG's implants are sterilized using a validated sterilization cycle using Gamma Radiation. The sterility assurance level (SAL) is  $10^{-6}$ .

The Gamma sterilization cycle is designed and validated according to ISO 11137-1 "Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices".

The established monitoring system comprises extensive routine controls including verification dose experiments, Bioburden and Endotoxin testing as well as periodic review of all parameters.

Waldemar Link GmbH & Co. KG's Gamma sterilized products are provided with five years product sterility, unless the packaging is damaged or products are stored under inappropriate conditions.