



Product Service

## Supplement to Quality System Certificate Q4N 16 11 70766 004

issued by TÜV SÜD PRODUCT SERVICE GMBH on 2017-01-20

**Herotron E-Beam Service GmbH**  
**Guardianstrasse 6-10**  
**06766 Bitterfeld-Wolfen**  
**Germany**

for the facility

**Herotron E-Beam Service GmbH**  
 Guardianstrasse 6-10, 06766 Bitterfeld-Wolfen, Germany

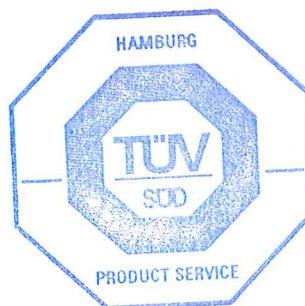
The quality system certified as stated above additionally fulfills the applicable requirements of **EN ISO 11137-1: 2015-11 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices** - as documented in the audit report no. 713080040 dated 2016-08-22.

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

This supplement is valid only together with the certificate stated above.

**TÜV SÜD PRODUCT SERVICE GMBH**  
**Certification Committee for Medical Devices**

Stefan Preiß  
 Munich, 2017-01-20



TÜV SÜD Product Service GmbH is a Notified Body (identification number 0123) according to Council Directive 93/42/ EEC concerning medical devices.

