



## ISO-CERTIFICATION

In compliance to EU statutory provisions the design, the production, the distribution and the after sales maintenance of medical products require a certification according to the international standard

### EN ISO 13485:2003

Caretec has been certified and approved according to the requirements of standard ISO 13485:2003 by the Austrian Technical Inspection Authority - TÜV Austria – and is therefore authorized to design and produce medical products according to EU Directive 98/79/EC for In-Vitro-Diagnostic.

In the course of this certification all departments involved in the quality-related processes have been inspected by the Notified Body. It has been confirmed, that the products are designed and produced in compliance with statutory provisions and EU directives.

The following certificates have been issued by the TÜV Austria:

**TÜV certificate for ISO 13485:2003**

**TÜV certificate for directive 98/79/EG  
(annex IV chapter 3 – In-Vitro-Diagnostic)**

TÜV-A-MT-1/06/E064

TÜV-A-MT-1/06/IQ004



EN ISO 13485:2003  
E064



98/79/EG Anh.IV  
IQ004