



ACCREDITATION

The Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) confirms that

**Medizinische Hochschule Hannover
Klinik für Hämatologie, Hämostaseologie, Onkologie und
Stammzelltransplantation**

**Carl-Neuberg-Straße 1
30625 Hannover
Germany**

is competent under the terms of

**Council Directives 93/42/EEC, 90/385/EEC and
EN ISO 15189**

for

Clinical chemistry (including hematology, haemostaseology)

This accreditation is valid up to **2014-11-16**.

This document is valid only in conjunction with the accreditation notice which contains the binding information on the accreditation. The scope of the accreditation is specified in the annex in force of the accreditation notice and can be found on www.zlg.de, tab accredited bodies, laboratories.

Registration number **ZLG-P-345.09.08**

Bonn, 2009-11-17

Dr. Undine Soltau
Director of ZLG



Basis of accreditation

Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Official Journal L 189 of 20 July 1990, p 17; last amended by Directive 2007/47/EC of the European Parliament and of the Council of 05 September 2007, Official Journal L 247 of 21 September 2007, p 21

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Official Journal L 169 of 12 July 1993, p 1; last amended by Directive 2007/47/EC of the European Parliament and of the Council of 05 September 2007, Official Journal L 247 of 21 September 2007, p 21

German Act on Medical Devices (Medical Devices Act) of 02 August 1994 in the amended version of 07 August 2002 (BGBl. I p 3147); last amended by article 6 of the act of 29. July 2009 (BGBl. I p 2326)

Rules for accreditation of ZLG (www.zlg.de, Download)

- General Rules for Accreditation and Designation (200_AR01)
- Rules for the Accreditation of Laboratories (210_AR01)

EN ISO 15189 : 2007-04

Medical laboratories - Particular requirements for quality and competence

For the use of indications on the status of accreditation and designation the document of ZLG 200_HI02 applies (www.zlg.de, Download).