

1504



Product Safety and Quality Certification Department

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Cologne, May 25, 2009

Application for : Vollst. QMS, Anhang IV, IVD

Certificate No.

: HL 60022694 SHEET 0001

Techn. appliance : Only for QM-System audit

Test requirements: 98/79/EG

Dear Madame or Sir,

The technical documentation TF 056, Version 01 as of May 20, 2009 was reviewed. The On-Call Advanced Blood Glucose Test System is covered by the conformity assessment according to Directive 98/79/EC, Annex IV.3.

A change of the certificate No. HL 60022694 0001 is not necessary. The On-Call Advanced Blood Glucose Test System is covered by the scope of the certificate. The On-Call Advanced Lancets are covered by the conformity assessment according to Directive 93/42/EEC, Annex II.3 as well. An update of the certificate with registration no. HD 60022696 0001 is also not necessary.

Kind regards

Certification body

Test sample: no, documentation available

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