Conformity assessment procedures to CE marking

ANNEX II
List
A

- **Blood groups A, B, O, Rhesus, Kell**
- **HIV 1/2, HTLV I/II, hepatitis B, C, D**

ANNEX IV

- Full Quality Assurance system (ISO 9001/ EN 46001/EN/ISO 13485)
- Including section IV.4 - Examination of the design of the product
- And including section IV.6 - Verification of manufactured products (batch to batch control)

ANNEX V

- EC type-examination

ANNEX VII

- Production Quality Assurance (ISO 9002/EN 46002/EN/ISO 13488)
- Including Annex VII.5 - Verification of manufactured products (batch to batch control)

SELF-
TESTING
Devices for self-testing

ANNEX III
(section 1 to 6)

- EC Declaration of conformity
- EC Design-examination

IDEM ANNEX II
List A

IDEM ANNEX II
List B

ANNEX IV

- Full Quality Assurance system (ISO 9001/EN 46001/EN/ISO 13488)
- Without sections IV.4 and IV.6

ANNEX VII

- Production Quality Assurance (ISO 9002/EN 46002/EN/ISO 13488)
- Without section VII.5

ANNEX VI

- EC verification

ANNEX V

- EC type-examination

ANNEX II
LIST
B

- Blood groups Duffy, Kidd
- Irregular anti-erythrocytic antibodies
- Rubella, toxoplasmosis
- Phenylketonuria
- CMV, Chlamydia
- HLA DR, A, B
- PSA
- Trisomy 21
- Blood glucose meter for selfdiagnostic

ANNEX III
(Sections 1 to 5)

- EC Declaration of conformity
- Preparation of the technical documentation
- Obligation to follow the principles of quality assurance
- Systematic procedure to review experience gained from devices in the post-production phase

OTHER
Devices