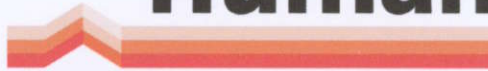


# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith grants

## Human



**Gesellschaft für Biochemica und Diagnostica mbH**  
**Max-Planck-Ring 21**  
**65205 Wiesbaden**  
**Germany**

for the scope

**HBsAg ELISA**  
**for the detection of HBs Antigen**

the

## EC Design Examination Certificate

The examination of the design of the product by mdc has proven,  
that the design meets the requirements according to

### Annex IV – Section 4 of the Council Directive 98/79/EC

of the European Parliament and of the Council of  
27 October 1998 on in vitro diagnostic medical devices.

This certificate is only valid in connection with a valid  
mdc certificate according to Annex IV – Section 3 for the above mentioned products.

|                                  |              |
|----------------------------------|--------------|
| This certificate is valid until: | 2013-11-28   |
| Certificate registration no:     | 0063.32.05/0 |
| Stuttgart                        | 2008-11-28   |

Head of  
Certification Body



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZE-629.00.17-IVD