

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that



**Hain Lifescience GmbH**  
**Hardwiesenstraße 1**  
**72147 Nehren**  
**Germany**

for the scope

**GenoQuick HLA-B27, Version 2.0, assay for the biomolecular  
detection of the human HLA-B27 gene from whole blood for diagnosis of  
associated illnesses, especially Bechterew's disease**

has introduced and applies a

**Quality System**

for the design, manufacture and final inspection.

The mdc audit has proven, that this quality system  
meets all requirements according to

**Annex IV – Section 3**  
**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.

The surveillance will be held as specified in Annex IV, Section 5.

This certificate is valid until:	2013-05-15
Certificate registration no:	0096.21.01/0
Stuttgart	2008-05-15

A handwritten signature in blue ink, appearing to read "P. Maurer".

Head of  
Certification Body



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