

Certificate

mdc medical device certification GmbH
certifies that

Astra Biotech GmbH
Im Biotechnologiepark, TGZ I
14943 Luckenwalde
Germany

for the scope

manufacture and distribution of in vitro diagnostics

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

(EN ISO 13485:2003 + AC:2009)

Valid from	2011-02-08
Valid until	2016-02-08
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Head of Certification Body



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