EC Certificate

mdc medical device certification GmbH

Notified Body 0483 herewith grants

aj ROBOSCREEN

AJ Roboscreen GmbH Delitzscher Straße 135 04129 Leipzig Germany

for the scope

RoboGene® HCV RNA Quantification Kit

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 – excluding section 4 and 6 for the above mentioned products.

Valid from 2012-06-20 Valid until 2017-06-20 Registration no. 1054.32.02/0

Report no. E 1054.32 / 2012-06-20

Stuttgart 2012-06-20

Head of Certification Body





Internet: http://www.mdc-ce.de