

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**Demeditec Diagnostics GmbH
Lise-Meitner-Straße 2
24145 Kiel
Germany**

for the scope

**ELISA tests for evaluating the risk of trisomy 21
PAPP-A, REF DE52051
beta-hCG free, REF DE4718**

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 – excluding Section 4 and 6
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.

Valid from	2018-01-08
Valid until	2023-01-07
Registration no.	D1355700006
Report no.	P17-01109-103265
Stuttgart	2018-01-08


Head of Certification Body



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bei Arzneimitteln und
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