

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

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for the scope

**Immuno-chromatographic test for determination of Chlamydia trachomatis antigen  
Chlamydia trachomatis controls  
Rapid self-testing device for detection of Helicobacter pylori in stool sample**

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	2022-04-13
Valid until	2025-05-26
Registration no.	D1016000052
Report no.	P21-00806-235224
Stuttgart	2022-04-13



Head of Certification Body

