

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**Curetis GmbH  
Max-Eyth-Straße 42  
71088 Holzgerlingen  
Germany**

for the scope

**Unyvero HPN Hospitalized Pneumonia Cartridge Set - multiplex PCR for  
molecular diagnostic detection of Chlamydia pneumoniae**

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	2021-04-23
Valid until	2021-10-23
Registration no.	D1413800007
Report no.	P21-00021-195213
Stuttgart	2021-03-04



Head of Certification Body

