

# 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 pneumonia-associated  
pathogens (including Chlamydia pneumoniae) and related  
antibiotic resistance conferring genes**

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	2022-05-09
Valid until	2025-05-26
Registration no.	D1413800010
Report no.	P21-02095-224230
Stuttgart	2022-05-09

  
Head of Certification Body



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bei Arzneimitteln und  
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