

Hiermit erklären wir in alleiniger Verantwortung, dass das folgende Produkt:
We declare in sole responsibility, that the following product:

Produktbezeichnung:

Product Name:

Unyvero HPN Hospitalized Pneumonia Cartridge Set

Produktkategorie:

Product category:

PCR basiertes IVD für die Detektion von pathogen-spezifischen und resistenzassoziierten Genen in Proben aus dem respiratorischen Trakt

PCR based IVD for the detection of pathogen specific and resistance associated genes in samples of the respiratory tract

GMDN-Code:

Curetis Produkt <i>Curetis Product</i>	GMDN Code	Nomenklatur <i>Nomenclature</i>
Unyvero HPN Hospitalized Pneumonia Cartridge Set	60764	Multiple respiratory disease-associated bacteria/antimicrobial resistance nucleic acid IVD, kit, nucleic acid technique

Hersteller:

Curetis GmbH

Manufacturer:

Max-Eyth-Straße 42
71088 Holzgerlingen
Germany

eingestuft ist als In-vitro-Diagnostikum gemäß Anhang II, Liste B der Richtlinie 98/79/EG
is classified as an in-vitro diagnostic medical device according to Annex II, list b of the Directive 98/79/EC

und gefertigt wird gemäß den Vorgaben der Richtlinie 98/79/EG vom 27. Oktober 1998.
and is manufactured following the regulations of the Directive 98/79/EC dated October 27th, 1998.

Die „Grundlegenden Anforderungen“ gemäß Anhang I der Richtlinie 98/79/EG sind erfüllt.
The Essential Requirements of Annex I of the Directive 98/79/EC are fulfilled.

Konformitätsbewertungsverfahren nach Anhang IV - ohne Abschnitt 4 und 6 der Richtlinie 98/79/EG unter Einbezug der benannten Stelle:
Conformity assessment according Annex IV - excluding Section 4 and 6 of the Directive 98/79/EC taking into account of a notified body:

Benannte Stelle:

mdc medical device certification GmbH

Notified Body:

Kriegerstraße 6
70191 Stuttgart
Deutschland / Germany
Kennnummer / *Identification number:* 0483

Gültigkeitsdauer der Konformitätserklärung:

Validity of the Declaration of Conformity:

Gültig ab: 29. April 2022

Valid from: April 29th, 2022

Gültig bis: 26. Mai 2025

Valid until: May 26th, 2025

Die Konformitätserklärung umfasst folgendes Produkt und seine Komponenten:

The following product and its components are covered by the Declaration of Conformity:

Produkt <i>Product</i>	Artikelnummer <i>Article Number</i>
Unyvero HPN Hospitalized Pneumonia Cartridge Set	10047
Komponenten <i>Components</i>	Artikelnummer <i>Article Number</i>
12 x Unyvero HPN Hospitalized Pneumonia Cartridge	10046
1 x Unyvero T1 Sample Tube & Unyvero T1 Sample Tube Cap Set contains: <ul style="list-style-type: none"> 12x Unyvero T1 Sample Tube & Unyvero T1 Sample Tube Cap, # 10066 	10069
1 x Unyvero T1 Sample Transfer Tool Set contains: <ul style="list-style-type: none"> 12x Unyvero T1 Sample Transfer Tool, # 10005 	10014

29-Apr-2022

Datum
Date

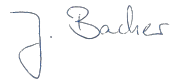


Karsten Müller
Head of Quality & Regulatory Affairs

Digitally signed by Karsten Klaus Müller
Reason: I am the approver
Date: 2022-04-29 10:14:49+02:00

29-Apr-2022

Datum
Date



Johannes Bacher
Managing Director

Digitally signed by Johannes Bacher
Reason: I am the approver
Date: 2022-04-29 10:28:22+02:00

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

To whom it may concern

Holzgerlingen, 25-Sep-2023

First Amendment to the Declaration of Conformity according to IVDD 98/79/EC

for the product

Product Name: **Unyvero HPN Hospitalized Pneumonia Cartridge Set**


Reference Number #10047

signed on 29-Apr-2022

The document is amended as follows:

Basic UDI: 42603647510047KR

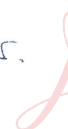
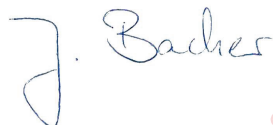
25-Sep-2023

 Digitally signed by Karsten Klaus Müller
Reason: I am the approver
Date: 2023-09-25 15:59:07+02:00

Date

Karsten Müller
Head of Quality & Regulatory Affairs, PRRC Curetis GmbH

09-Oct-2023

 Digitally signed by Johannes Bacher
Reason: I am the approver
Date: 2023-10-09 15:04:10+02:00

Date

Johannes Bacher
Managing Director Curetis GmbH