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 *Curetis Product*	GMDN Code	Nomenklatur *Nomenclature*
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 *Product*	Artikelnummer *Article Number*
Unyvero HPN Hospitalized Pneumonia Cartridge Set	10047
Komponenten *Components*	**Artikelnummer** *Article Number*
12 x Unyvero HPN Hospitalized Pneumonia Cartridge	10046
1 x Unyvero T1 Sample Tube & Unyvero T1 Sample Tube Cap Set contains: • 12x Unyvero T1 Sample Tube & Unyvero T1 Sample Tube Cap, # 10066	10069
1 x Unyvero T1 Sample Transfer Tool Set contains: • 12x Unyvero T1 Sample Transfer Tool, # 10005	10014

29-Apr-2022

Datum
Date

K. Müller

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

Karsten Müller
Head of Quality & Regulatory Affairs

29-Apr-2022

Datum
Date

J. Bacher

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

Johannes Bacher
Managing Director

Curetis GmbH is an OpGen group company.

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Website: www.curetis.com

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: 426036475100047KR

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