

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

Produktbezeichnung:

Product Name:

Unyvero BCU Blood Culture Cartridge Set

Produktkategorie:

Product category:

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

PCR based IVD for the detection of pathogen specific and resistance associated genes in blood cultures

GMDN-Code:

Curetis Produkt <i>Curetis Product</i>	GMDN Code	Nomenklatur <i>Nomenclature</i>
Unyvero BCU Blood Culture Cartridge Set	62484	Multiple-type bloodstream pathogen nucleic acid IVD, kit, nucleic acid technique (NAT)

Hersteller:

Manufacturer:

Curetis GmbH
Max-Eyth-Straße 42
71088 Holzgerlingen
Germany

eingestuft ist als In-vitro-Diagnostikum gemäß Anhang III ohne Auslegungsprüfung (Nr.6) der Richtlinie 98/79/EG

is classified as an in-vitro diagnostic medical device according to Annex III without examination of the design (No. 6) 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 III ohne Auslegungsprüfung (Nr.6) der Richtlinie 98/79/EG

Conformity assessment according Annex III without examination of the design (No. 6) of the Directive 98/79/EC

Gültigkeitsdauer der Konformitätserklärung:

Validity of the Declaration of Conformity:

Gültig ab: 29. April 2022

Valid from: April 29th, 2022

Gültig bis: 26. Mai 2026

Valid until: May 26th, 2026

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 BCU Blood Culture Cartridge Set	10051
Komponenten <i>Components</i>	Artikelnummer <i>Article Number</i>
12 x Unyvero BCU Blood Culture Cartridge	10050
1 x Unyvero B1 Sample Tube & Unyvero B1 Sample Tube Cap Set contains: <ul style="list-style-type: none"> 12x Unyvero B1 Sample Tube & Unyvero B1 Sample Tube Cap, # 10067 	10068
1 x Unyvero B1 Collection Tube Set contains: <ul style="list-style-type: none"> 12x Unyvero B1 Collection Tube, # 10058 	10061

29-Apr-2022

Datum
Date

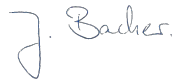


Karsten Müller
Head of Quality & Regulatory Affairs


 Digitally signed by Karsten Klaus Müller
Reason: I am the approver
Date: 2022-04-29 10:15:39+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 10:47:01+02:00

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

To whom it may concern

Holzgerlingen, 05-Oct-2023

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

for the product

Product Name: **Unyvero BCU Blood Culture Cartridge Set**


Reference Number #10051

signed on 29-Apr-2022

The document is amended as follows:

Basic UDI: 426036475 10051 KG

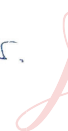
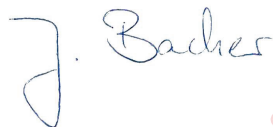
05-Oct-2023

 Digitally signed by Karsten Klaus Müller
Reason: I am the approver
Date: 2023-10-05 15:36:51+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 14:49:20+02:00

Date

Johannes Bacher
Managing Director Curetis GmbH