

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

Produktbezeichnung:

Product Name:

Unyvero UTI Urinary Tract Infection Cartridge Set

Produktkategorie:

Product category:

PCR basiertes IVD für die Detektion von pathogen-spezifischen und resistenzassoziierten Genen in Proben mit Verdacht auf Harnwegsinfektionen

PCR based detection of IVD for the pathogen-specific and resistance associated genes in the sample with a suspected urinary tract infection

GMDN-Code:

Curetis Produkt <i>Curetis Product</i>	GMDN Code	Nomenklatur <i>Nomenclature</i>
Unyvero UTI Urinary Tract Infection Cartridge Set	65139	Multiple urinary tract 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 UTI Urinary Tract Infection Cartridge Set	10079
Komponenten <i>Components</i>	Artikelnummer <i>Article Number</i>
12 x Unyvero UTI Urinary Tract Infection Cartridge	10078
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 Pre-Treatment Tool Set contains: <ul style="list-style-type: none"> 12x Unyvero T1 Sample Pre-Treatment Tool, # 10042 	10043

29-Apr-2022

Datum
Date

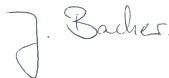


Karsten Müller
Head of Quality & Regulatory Affairs

Digitally signed by Karsten Klaus Müller
Reason: I am the approver
Date: 2022-04-29 10:26:18+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 11:03:11+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 UTI Urinary Tract Infection Cartridge Set**


Reference Number #10079

signed on 29-Apr-2022

The document is amended as follows:

Basic UDI: 426036475 10079 L6

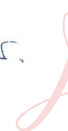
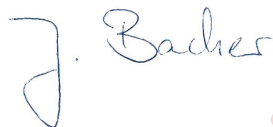
05-Oct-2023

 Digitally signed by Karsten Klaus Müller
Reason: I am the approver
Date: 2023-10-05 15:43:13+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 14:54:15+02:00

Date

Johannes Bacher
Managing Director Curetis GmbH