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

Produktbezeichnung:
Product Name:
Unyvero ITI Implant & Tissue Infection Cartridge Set

Produktkategorie:
Product category:
PCR basiertes IVD für die Detektion von pathogen-spezifischen und resistenzassoziierten Genen in Proben mit Verdacht auf Gewebe- und Implantationsinfektionen
PCR based detection of IVD for the pathogen-specific and resistance associated genes in the sample with a suspected tissue and implant infection

GMDN-Code:

Curetis Produkt *Curetis Product*	GMDN Code	Nomenklatur *Nomenclature*
Unyvero ITI Implant & Tissue Infection Cartridge Set	61529	Multiple tissue pathogenic bacteria 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 *Product*	Artikelnummer *Article Number*
Unyvero ITI Implant & Tissue Infection Cartridge Set	10041
Komponenten ***Components***	**Artikelnummer** ***Article Number***
12x Unyvero ITI Implant & Tissue Infection Cartridge	10040
1x Unyvero T1 Sample Tube & Unyvero T1 Sample Tube Cap Set contains: • 12x Unyvero T1 Sample Tube & Unyvero T1 Sample Tube Cap, # 10066	10069
1x Unyvero T1 Sample Pre-Treatment Tool Set contains: • 12x Unyvero T1 Sample Pre-Treatment Tool, # 10042	10043

29-Apr-2022

Datum
Date

K. Müller

Digitally signed by Karsten Klaus Müller
Reason: I am the approver
Date: 2022-04-29 10:22:46+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 10:57:42+02:00

Johannes Bacher
Managing Director

Curetis GmbH is an OpGen group company.

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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 ITI Implant & Tissue Infection Cartridge Set**

Reference Number #10041

signed on 29-Apr-2022

The document is amended as follows:

Basic UDI: 426036475 10041 KD

05-Oct-2023

Digitally signed by Karsten Klaus Müller
Reason: I am the approver
Date: 2023-10-05 15:41:57+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 14:52:48+02:00

Date

Johannes Bacher
Managing Director Curetis GmbH