

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 <i>Curetis Product</i>	GMDN Code	Nomenklatur <i>Nomenclature</i>
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 29<sup>th</sup>, 2022*

Gültig bis: 26. Mai 2026

*Valid until: May 26<sup>th</sup>, 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 ITI Implant & Tissue Infection Cartridge Set	10041
Komponenten <i>Components</i>	Artikelnummer <i>Article Number</i>
12x Unyvero ITI Implant & Tissue Infection Cartridge	10040
1x Unyvero T1 Sample Tube & Unyvero T1 Sample Tube Cap Set contains: <ul style="list-style-type: none"> <li>12x Unyvero T1 Sample Tube &amp; Unyvero T1 Sample Tube Cap, # 10066</li> </ul>	10069
1x Unyvero T1 Sample Pre-Treatment Tool Set contains: <ul style="list-style-type: none"> <li>12x Unyvero T1 Sample Pre-Treatment Tool, # 10042</li> </ul>	10043

29-Apr-2022

Datum  
*Date*

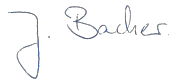


Karsten Müller  
*Head of Quality & Regulatory Affairs*

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

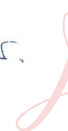
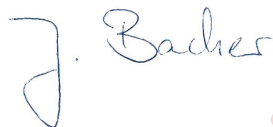
05-Oct-2023

 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*