

EU-Declaration of Conformity

as per Annex IV of the Regulation EU 2017/746
 on in-vitro diagnostic medical devices

Manufacturer Address: Curetis GmbH
 Max-Eyth-Straße 42
 71088 Holzgerlingen
 Germany

Single Registration Number: DE-MF-000024064

Curetis GmbH declares, in its sole responsibility, that the product / the product line

Product Name:	Unyvero M1 Master Mix Tube Set
Article No.:	10011
Basic UDI-DI:	426036475 10011 K4
Risk Class:	<input checked="" type="checkbox"/> A / <input type="checkbox"/> B / <input type="checkbox"/> C / <input type="checkbox"/> D
Intended Purpose:	<p>The IVD medical device Unyvero M1 Master Mix Tube Set is a reagent used for DNA amplification in multiplex PCR assays of human specimen to detect the presence of infectious agents, toxins and antibiotic resistance genes.</p> <p>It may only be used in combination with Unyvero Applications and Unyvero System instruments and is intended to be used by trained healthcare professionals in a laboratory environment.</p>
Conformity Route:	<input checked="" type="checkbox"/> Self-Declaration of Conformity (Class A) <input type="checkbox"/> Self-Declaration of Conformity after Notified Body involvement for sterile manufacturing conditions acc. Art. 48 (10) (Class A sterile) <input type="checkbox"/> Technical Documentation Assessment Class B/C – Annex IX <input type="checkbox"/> Technical Documentation Assessment Class D – Annex IX <input type="checkbox"/> Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX <input type="checkbox"/> Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX <input type="checkbox"/> Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX
Certificates:	<input type="checkbox"/> EU QM Certificate No.: not applicable <input type="checkbox"/> EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): not applicable
Other:	<input type="checkbox"/> Common Specifications: not applicable
Notified Body (NB) Name:	not applicable
Notified Body Address:	not applicable

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Notified Body Ident. No.:	not applicable
Valid until:	not applicable

to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Holzgerlingen,

25-Sep-2023

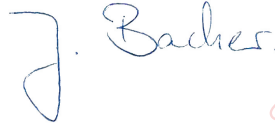


Digitally signed by Karsten Klaus Müller
Reason: I am the approver
Date: 2023-09-25 16:10:50+02:00

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 15:00:25+02:00

Date

Johannes Bacher
Managing Director Curetis GmbH