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:	☒ A / ☐ B / ☐ C / ☐ D
Intended Purpose:	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. 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.
Conformity Route:	☒ Self-Declaration of Conformity (Class A) ☐ Self-Declaration of Conformity after Notified Body involvement for sterile manufacturing conditions acc. Art. 48 (10) (Class A sterile) ☐ Technical Documentation Assessment Class B/C – Annex IX ☐ Technical Documentation Assessment Class D – Annex IX ☐ Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX ☐ Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX ☐ Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX
Certificates:	☐ EU QM Certificate No.: not applicable ☐ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): not applicable
Other:	☐ Common Specifications: not applicable
Notified Body (NB) Name:	not applicable
Notified Body Address:	not applicable

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