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 System
Article No.:	Unyvero A50 Analyzer # 60001 Unyvero L4 Lysator # 60002 Unyvero C8 Cockpit # 60003 (including the Unyvero Software) Unyvero Sample Tube Holder # 60010 (accessory)
Basic UDI-DI:	Unyvero A50 Analyzer: 426036475 60001 LQ Unyvero L4 Lysator: 426036475 60002 LS Unyvero C8 Cockpit: 426036475 60003 LU Unyvero Sample Tube Holder: 426036475 60010 LR
Risk Class:	☒ A / ☐ B / ☐ C / ☐ D
Intended Purpose:	The Unyvero System is an automated PCR-based in vitro diagnostic (IVD) device intended for use solely with Unyvero Applications to qualitatively detect multiple nucleic acid targets contained in clinical specimens to aid in the diagnosis of infections and associated antibiotic resistances. The Unyvero System processes the Unyvero Cartridges (including cartridge specific master mix and consumables) to extract, amplify and detect targeted nucleic acid sequences in a closed system. It automatically generates and displays test results. The Unyvero System is intended to be used by trained healthcare professionals in a laboratory environment. The Unyvero System includes the following components: • Unyvero A50 Analyzer • Unyvero L4 Lysator • Unyvero C8 Cockpit (incl. Unyvero OS and Unyvero Application specific Plug-Ins) • Unyvero Sample Tube Holder
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

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	☐ 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 and Directive 2011/65/EU (RoHS).

Holzgerlingen,

25-Sep-2023

Digitally signed by Karsten Klaus Müller
Reason: I am the approver
Date: 2023-09-25 16:00:14+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 15:02:26+02:00

Date

Johannes Bacher
Managing Director Curetis GmbH