

EU DECLARATION OF CONFORMITY

The undersigned, representing the following manufacturer:

Manufacturer: Taigen Bioscience Corp.
3F., No. 150, Sec. 4, Chengde Rd.,
Taipei, Taiwan, R.O.C.

Representative: David Daf
Function: General Manager (PRRC)

Declare under our sole responsibility that the devices listed in the attached Annex comply the following in vitro diagnostic medical devices meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices.

Conformity assessment was performed according to Article 48 of IVDR.

Our current Quality System is formatted to international standards:

IEC 61010-1:2001, IEC 61010-2-010:2003, IEC 61010-2-081am1:2003, IEC 61010-2-101:2002, IEC 61326-2-6:2006/ IEC 61326-1:2005, EN ISO 14971:2012, EN ISO 13485:2016, EN ISO 13612:2002, EN ISO 18113:2011

Guidance for Industry and FDA Staff-Class II Special Controls Guidance Document:RNA Preanalytical System(RNA Collection, Stabilization and Purification Systems for RT-PCR used in Molecular Diagnostic Testing)

Document issued on: August 25, 2005

“Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guidelle”(2004) CLSI Document EP5-A2,

“Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guidelle” CLSI Document EP6-A.

Signature

A handwritten signature in blue ink, consisting of a cursive name followed by a large, stylized flourish.

2022-07-01

Taipei, Taiwan

This Conformity is indicated by the symbol **CE**, i.e. “Conformité européenne”

Authorised Representative in the European Economic Area (incl. European Union and EFTA member states):

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Annex- List of Devices

#	Catalogue reference number	Commercial Name	Short description and intended use	GMDN / GIVD Code	Class and Rule under IVDR	Basic UDI-DI
1	C2420/LabTurbo 24 Compact System; C4820/LabTurbo 48 Compact System	LabTurbo Automated Nucleic Acid Purification System	Full automation for nucleic acid extraction	26.02.10.01	Rule 5 (b), Class A	471510428LT2448YB
2	24C-LGD480-220; 24C-LGD480-300; 24C-LGD480-500; 24C-LGD480-1000; 24C-LGD480-2000; LGD480-220; LGD480-300; LGD480-500; LGD480-1000; LGD480-2000; 45X-LGD480-2000	LabTurbo DNA Mini Kit	Kit for genomic DNA extraction	15.90.40.01	Rule 5 (a), Class A	471510428LGD480XF
3	24C-LVX480-300; 24C-LVX480-500; 24C-LVX480-1000; LVX480-300; LVX480-500; LVX480-1000	LabTurbo Viral DNA/RNA Mini Kit	Kit for viral DNA + RNA extraction	15.90.40.01	Rule 5 (a), Class A	471510428LVX48093