MP Biomedicals Asia Pacific Pte Ltd
Co Regn No. 198403141W

2 Pioneer Place
Singapore 627885

Tel : 65-6775 0008
Fax : 65-67746146 (Sales)
65-6862 3565 (General)
Web : www.mpbio.com

EU DECLARATION OF CONFORMITY

MANUFACTURER:	MP Biomedicals Asia Pacific Pte. Ltd. 2 Pioneer Place, Singapore 627885
EUROPEAN REPRESENTATIVE:	MP Biomedicals Germany GmbH Thüringer Straße 15 37269 Eschwege Germany Telephone No.: (49) 5651 921 204 Facsimile No.: (49) 5651 921 181 E-mail: diagnostics@mpbio.com
PRODUCT AND TRADE NAME:	MP Diagnostics MPure-32 aNAP System Catalogue Number: EMC043
BASIC UDI-DI:	08887581002225
CLASSIFICATION:	Class A, Rule 5
EDMA CLASSIFICATION:	28.01.10.01 SP Hardware + accessories + consumables + software
GMDN CODE	60736 Nucleic acid sample preparation instrument IVD, automated
CONFORMITY ASSESSMENT ROUTE:	Self-Declaration ANNEX II, III

WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCT FULFIL THE GENERAL SAFETY AND PERFORMANCE REQUIREMENTS OF ANNEX I AND MEETS THE PROVISIONS OF THE COUNCIL REGULATION (EU) 2017/746 FOR IN-VITRO DIAGNOSTIC MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THIS EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER.

STANDARDS APPLIED:	List of Applied Standards referred to Appendix 1
PLACE, DATE OF ISSUE:	Singapore, 2022-05-19
REVISION:	1
SIGNATURE:	Anita Chuang Yi-Lun Anita Chuang Yi-Lun (May 19, 2022 15:35 GMT+8) QA/RA Manager (Person responsible for regulatory compliance) email: anita.chuang@mpbio.com

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Appendix 1: List of Applied Standards

Standards	Title
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-3:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
IEC 61010-1:2010	Safety requirements of electrical equipment for measurement, control and laboratory use – part 1: general requirements
EN 61010-2-101:2002	Safety requirements of electrical equipment for measurement, control and laboratory use – part 2-101: Particular requirements in vitro diagnosis (IVD) medical equipment
IEC 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
IEC 61326-2-6:2012	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
IEC 62304:2015	Medical device software – software life cycle processes
IEC 62366-1: 2015	Medical devices – Part 1: Application of usability engineering to medical devices