

NICHIRYO CO.,LTD.

Declaration of Conformity

Manufacturer:	NICHIRYO CO.,LTD.	
Address:	2760-1,Nishikata,Koshigaya-shi,Saitama,343-0822,Japan	
SRN:	JP-MF-000027144	
European Authorized Representative:	Emergo Europe	
Address:	Westervoortedijk 60, 6827 AT Arnhem, The Netherlands	
SRN:	NL-AR-000000116	
Product(s):	Nichiryo Pipettes	
Basic UDI-DI	BASIC UDI-DI 458951424NichiryoTH	
Product Name / Model No.:	Nichipet Air	00-NAR-2,10, 20,100, 200,1000, 5000,10000 10M8,10M12,100M8,100M12,200M8, 200M12,300M8,300M12
	Nichipet Premium	00-NPP-2,10, 20,100, 200,1000, 5000,10000
	Nichipet Premium LT	00-NLT-2,10, 20,100, 200,1000
	Nichipet EXII	00-NPX2-2,10, 20,100, 200,1000, 5000,10000
	Nichipet EX Plus II	00-NPLO2-2,10, 20,100, 200,1000, 5000,10000
	Nichiryo Le	00-NLE-10, 20,100, 200,1000
	Nichipet EXII MULTI	00-NPM-8V,8S 8L,8K,12V,12S,12L,12K
	Nichipet EXIII	00-NPX3-2,10, 20,100, 200,1000, 5000,10000
Intended Use	Nichiryo pipette family (hereinafter, this is called "Nichiryo Pipettes"), used in conjunction with pipette tip recommended by Nichiryo, are designed and constructed for low-contamination transfer of liquids, especially for samples from the human body and for reagents within the scope of an in-vitro diagnostic application in order to allow the in-vitro diagnostic medical device to be used as intended. Nichiryo Pipettes are intended exclusively for indoor use and for operation by qualified staff.	
Applicable Product Units:	Serial No. 22400011 or later	
Classification (IVDR, Annex VIII):	Class A(Rule 5(a))	
Conformity Assessment Procedure:	Annex II and III	
Applied Common Specification:	N/A	
Applied Standards:	See Attachment "NP-R746 Technical documentation"	

We herewith declare that the above mentioned product(s) meets the provisions of the Regulation (EU) 2017/746 for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

Notified Body:N/A

EU Quality Management System Certificate: N/A

Place 2760-1,Nishikata,Koshigaya-shi,Saitama,343-0822,Japan

Date 4/2/2025



No. NP-R746-8-1