

NICHIRYO CO.,LTD.

Declaration of Conformity

Manufacturer: NICHIRYO CO.,LTD.
Address: 2760-1,Nishikata,Koshigaya-shi,Saitama,
343-0822,Japan
SRN: JP-MF-000027144

Authorised Representative: Emergo Europe B.V.
Address: Prinsessegracht 20 2514 AP,Thr Hague
The Netherlands
SRN: NL-AR-000000116
Product(s): Nichiryo Pipettes
Basic UDI-DI BASIC UDI-DI 458951424NichiryoTH
Model No.: 00-NAR-2,10, 20,100, 200,1000, 5000,10000
10M8,10M12,100M8,100M12,200M8
200M12,300M8,300M12
00-NPP-2,10, 20,100, 200,1000, 5000,10000
00-NLT-2,10, 20,100, 200,1000
00-NPX2-2,10, 20,100, 200,1000, 5000,10000
00-NPLO2-2,10, 20,100, 200,1000, 5000,10000
00-NLE-10, 20,100, 200,1000
00-NPM-8V,8S 8L,8K,12V,12S,12L,12K

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.

NICHIRYO CO.,LTD.

Notified Body:N/A

EU Quality Management System Certificate: N/A

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

Date 8/9/2022



Director, Management Headquarters