

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 Pipette Tips
Basic UDI-DI: BASIC UDI-DI 458951424NichiryoTH
Model No.: 00-BMT2-UT,UTWR,SSW,SSWR,SG,SGR
K,KR,LG,LGR,X,XR,Z,ZR,ZS,ZSR

Intended Use
Nichiryo Pipette Tips 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 Pipette Tips 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-R746T 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 8/ 9/2022



Director, Management Headquarters