



EU Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Nikon Corporation	471, Nagaodai-cho, Sakae-ku, Yokohama, Kanagawa 244-8533 Japan	JP-MF-000029301

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/Email
Nikon Europe B.V.	Stroombaan 14, 1181 VX Amstelveen, The Netherlands	NL-AR-000028107	+31-20-7099-000 MDR.eu@nikon.com

PRODUCT IDENTIFICATION		
Product / Trade Name	Product Code	Basic UDI-DI
ECLIPSE Si RS	MCA77200	4549921AA000MQ
Intended Purpose		
This microscope and accessories are optical instruments used to enlarge images of specimens, preparations, and cultures for medical purposes.		

IVDR RISK CLASS / STANDARDS / COMMON SPECIFICATIONS			
Device Classification		Standards	Common Specifications
Class	A	EN 61010-1:2010/A1:2019/AC:2019-04 EN 61010-2-101:2017 EN 62366-1:2015 EN 62304:2006 EN 62471:2008	N/A
Rule	5	EN 61326-1:2013 EN 61326-2-6:2013 EN IEC 63000:2018 EN ISO 14971:2012 EN ISO 13485:2016	

Nikon Corporation declares that the above-mentioned products meet the provision of the following EU legislation:

- In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746
- RoHS Directive (2011/65/EU, 2015/863/EU)

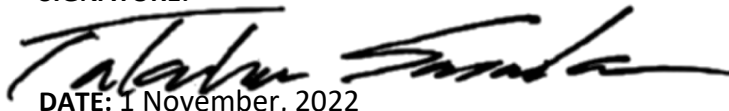
We, Nikon Europe B.V., Stroombaan 14, 1181 VX Amstelveen, The Netherlands, as the authorized representative, declare the conformity.

COMPANY REPRESENTATIVE: TAKAHARU SASAOKA

TITLE: Director & Executive Vice President
Healthcare Division Head

PLACE: AMSTELVEEN, THE NETHERLANDS

SIGNATURE:



DATE: 1 November, 2022