ID:DOC-MCA77200-EUR-01

# 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 | N/A |

| AUTHORIZED REPRESENTATIVE | | | |
|---|---|---|---|
| **Name of Company** | **Address** | **SRN** | **Telephone/email** |
| Nikon Europe B.V. | TRIPOLIS 100, BURGERWEESHUISPAD 101, 1076 ER AMSTERDAM, THE NETHERLANDS | N/A | +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/AC2019-04<br>EN 61010-2-101:2017<br>EN 62366-1:2015<br>EN 62304:2006<br>EN 62471:2008<br>EN 61326-1:2013<br>EN 61326-2-6:2013<br>EN IEC 63000:2018 | N/A |
| Rule | 5 | | |

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., TRIPOLIS 100, BURGERWEESHUISPAD 101, 1076 ER AMSTERDAM, THE NETHERLANDS, as the authorized representative, declare the conformity.

**COMPANY REPRESENTATIVE:** TAKAHARU SASAOKA

**TITLE:** Director & Executive Vice President
Healthcare Division Head

**SIGNATURE:**

**PLACE:** AMSTERDAM, THE NETHERLANDS

**DATE:** 10 May, 2022

Digitally signed by Potînga Stela
Date: 2023.08.24 13:34:44 EEST
Reason: MoldSign Signature
Location: Moldova