

DECLARATION OF CONFORMITY

The manufacturer,
NIDEK SA
Ecoparc
9 rue Benjamin Franklin
94 370 Sucy-en-Brie
SRN FR-MF-000000493

Declares that medical devices below:

Consultation Units
Reference AFFINITY (OT-2200)
Basic UDI 37008623UCO005BP

- are in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices and with any other relevant Union legislation ;
- are of the class I following the rule 13 of annex VIII of the Regulation (EU) 2017/745
- that the technical documentation defined in the annexes II and III of the Regulation (EU) 2017/745 has been established.

This declaration has been established under the sole responsibility of NIDEK SA.

Done to SUCY-EN-BRIE, At 08th June 2022

Yusuke TSUJI

General Director

**Règlement**

NIDEK SA - Banque Crédit du Nord - dom. CDN Beaubourg Entreprises - IBAN : FR76 3007 6021 6310 7688 0020 070 - BIC : NORDFRPP
SA au capital de 3811 225,43 € - R.C.S. Créteil B 344 082 144 - Siret 344 082 144 00082 - APE 4646 Z - id TVA FR 89 344 082 144

Assistance Technique

SAV Optique : 0820 200 998
SAV Ophtalmologie : 01 49 80 70 75
SAV Unités de consultation : 04 37 28 18 12

