

We, the company

Dumont Instruments & Co
Rue des Anciens Etangs 42,
B-1190 Forest

Hereby declare under our own responsibility that the following products

Carbide dental burs RA et FG (GMDN code 16-668)
Diamond dental burs RA et FG (GMDN code 16-670)

are class IIa medical device, in accordance with rule 5 of annex IX of Directive 93/42/EEC.

The quality control and conformity assessment procedures are carried out in accordance with the harmonized standard ISO 13485, audited by the notified body **KIWA CERMET ITALIA S.P.A., Via Cadriano, 23, 40057 - Cadriano di Granarolo (BO), Italie** and attested by a certificate (**Réf. – Nr 15088-M**)

A complete quality assurance system has been set up at DUMONT Instruments, audited, in accordance with Directive 93/42/EEC, Annex II, without point 4, by the notified body **KIWA CERMET ITALIA S.P.A. Via Cadriano, 23, 40057 - Cadriano di Granarolo (BO), Italy** and attested by a certificate (**Ref - Nr MED 31408**).

The validity period of the CE certificate is extended to December 2028, as per article 1(a)(a) of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746, as Dumont Instruments & Co is fully engaged in the transition to comply with Regulation (EU) 2017/745.

This declaration is valid from 20-03-2023, for all the products of the group mentioned above.

DUMONT Instruments & CO



Marc Johnen
CEO