

MEDICAL DEVICES DIVISION

Granarolo dell'Emilia (BO), 2023/04/18
CL2/V.2

Esteemed

DUMONT INSTRUMENTS & Co. S.a.
Rue des Anciens Etangs, 42
1190 Forêt - Brussels - Belgium

Letter Reference: MDR 00012

Subject: Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

To whom it may concern,

This letter confirms that, Kiwa Cermet Italia, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0476 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

DUMONT INSTRUMENTS & Co. S.a.
Rue des Anciens Etangs, 42
1190 Forêt - Brussels - Belgium

SRN Number: BE-MF-000004419

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 20 March 2023, this letter also confirms that the manufacturer submitted the MDR application and signed the written agreement by the date of MDD certificate expiry (date above indicated in the table).

Yours faithfully,

Kiwa Cermet Italia
Medical Devices Division
Manager

A handwritten signature in blue ink, appearing to read "Alessandro Fabetti".

Devices covered by this letter

Device name (under MDR agreement)	Basic UDI-DI (under MDR agreement)	Device classification under MDR
Carbide rotative dental instruments	54040342CARBDD	Ila
Diamond coated rotative dental instruments	54040342DIAMDX	Ila

The aforementioned devices are covered by the MDD certificate

ref: MED 31408, rev.1 expiry date 11/10/2022

Confirmation Letter Revision History

Rev.	Date	Action
00	2023/04/18	Initial issue

