

Esteemed

COSMOSOFT S.A.S.

REGISTRATION NUMBER: FR14441011988

Old Operative Site: 1, Rue Pierre Brossolette 92300 Levallois-Perret - France

New Operative Site: 26 Rue d'Armaillé 75017 Paris - France

Subject: Clearance Letter for "new operative site address" under the Certification Plan no. MED 31435 in compliance with the applicable requirements of Directive 93/42/EEC and subsequent amendments and additions

Dear Customer,

In accordance with Article 120, paragraph 3, of the MDR and with the guideline -MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD, the following change is considered as non-significant change.

Kiwa Cermet Italia, Notified Body N. 0476, following the positive results of evaluation conformity and decision-making activities reported above, is pleased to inform you that your company has achieved

the CE formal approval of the above modifications

as from the date of this communication, the placing on the market of the medical devices currently present in the

CE Certificate MED 31435, rev. 1, last modification date 08/02/2018

For which no further revision will be issued to what is currently in your possession, therefore it is to be considered in force.

We remind you to send us, on your company letterhead paper, the identification of the first medical devices batch that will be placed on the market following the modifications mentioned above.

Hoping the collaboration with Kiwa Cermet Italia can remain constructive and fruitful in the future, We remain at your disposal for any other needs you may have

Best Regards

Kiwa Cermet Italia
Medical Devices Division

Germana Paulillo

