

MEDICAL DEVICES DIVISION

Granarolo dell'Emilia (BO), 2026/06/05

Code: CERBO0842625

Esteemed

PREVIOUS **COMPANY NAME** : TONOLI S.r.l.

CURRENT **COMPANY NAME** : FEINROHREN S.p.A.

Previous VAT number: 03216680177

Current VAT number: 00551380983

Registered and Operational Headquarter: Via Generale Reverberi, 8 - 25050 Passirano (BS)

Operational Headquarter: Via F.lli Rosselli, 1 - 25050 Passirano (BS)

Subject: Clearance notice for "change Company name and VAT number" certification plan MED 31611 in accordance with the applicable requirements of Directive 93/42/EEC and s.a.

Dear Customer,

Kiwa Cermet Italia, Notified Body N. 0476, is pleased to inform that following the positive outcome of both documental assessment and decision-making process, the change of Company name and Vat number as mentioned above has been approved.

According to Art 120, indent 3, of MDR and to the 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 above change is considered as not-significant.

As a result of the above and by virtue of Art.120, paragraph 1, of the MDR, no further revision of the CE certificate currently in your possession will be issued, which remains valid and registered as:

CE Certificate MED 31611, rev. 0, last modification date 22/05/2020

Therefore, this clearance notice shall always be attached to the CE certificate as an integral part.

From the date of this communication your Company is allowed to implement the above changes and to put on the market the related medical devices.

We also remind you, it is mandatory to receive on your company letterhead paper, the identification of the first medical devices batch that will be placed on the market according to the following the change 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

Kind regards

**Kiwa Cermet Italia
Medical Devices Division**

Massimo Mazzullo

