BUSINESS LINE HEALTHCARE & MEDICAL DEVICE
Cadriano di Granarolo (BO)
2015-11-30

SUBJECT: information concerning "Unannounced Audits" performed by Kiwa Cermet Italia following the European Recommendation 2013/473/EU dated 24 September 2013

Dear Customer,
We wish to remind you that, regarding to the *European Commission Recommendation 2013/473/EU dated 24th September 2013 related to the audits and assessments performed by Notified Bodies in the field of medical devices*, the introduction of "**unannounced audits"** in addition to the initial, surveillance and renewal ones, to verify the day-to-day compliance with legal obligations. These audits should be performed at the manufacturer's premises and, if appropriate, at one of its suppliers in charge of processes essential for ensuring compliance with legal requirements or a crucial supplier producing medical device's components.

Consequently, and having regard to the Regulation RG.01 MED rev.6 of 2014/11/26 undersigned by your Company, **starting from December 2015**, KIWA CERMET ITALIA S.p.A. is going to perform unannounced audits at your Company, with a minimum frequency of at least one time every three years. The auditors, authorized by KIWA CERMET ITALIA S.p.A., with an authentication letter and badge, will arrive at your Company asking to access to your production site and/or your critical/crucial suppliers. The presence of the medical devices responsible manager and/or other operating functions should be requested during the visit. However, the absence of managers will not affect the delivery of the activities. In the event in which the access to sites, premises and information necessary to conduct unannounced audits should be denied, KIWA CERMET ITALIA S.p.A. shall proceed with the suspension and cancellation of certification.

In order to guarantee a correct delivery of unannounced audits, we would remind you to continuously inform us on the periods in which the devices reported in the EC certificate are not manufactured (production downtimes, business closures, holidays, supplier's closures, etc.). If we do not receive such information, we will plan and carry out the activities of unannounced audit any time of year. Please submit this information to the following email address medicaldevice@kiwacermet.it.

Finally, we would like to remind you that, as mentioned in the European Recommendation 2013/473/EU and in the contractual arrangements between your Company and KIWA CERMET ITALIA S.p.A., critical or crucial suppliers of medical devices have to be informed about unannounced audits in order to allow the access to their production sites.

For information and disclosure please find attached the 2013/473/EU Recommendation.

Thank you in advance for your cooperation, we remain at disposal for further clarification.

We are waiting to your kind reply

Best regards

Alessia Frabetti
Healthcare & Medical Devices
Business Line Manager