Kiwa Cermet Italia

Granarolo dell'Emilia, 2018/10/30
Business Sector Medical Devices

To the kind attention of Customers with an active certification plan in accordance with Directive 93/42/EEC

Object: ISSUING OF THE NEW EUROPEAN REGULATION 2017/745 AND VALIDITY OF CERTIFICATIONS RELATED TO THE DIRECTIVE 93/42/EEC

Dear Customer,

As known, the new European Regulation 2017/745 regarding Medical Devices (MD) entered into force on **26th May 2017**.

From this date and for the period of following 3 years, until 26th May 2020, the Directive 93/42/EEC will be applicable.

From **26th May 2020** the new Regulation 745 shall solely apply, so it is not possible to issue or extend new certificates in accordance with the old Directive, in addition it is not possible to modify the certificate related to the Directive, if this change concerns significant aspects with regards to the design of the MD or its intended use.

The certificates issued in accordance with the Directive 93/42/CEE:

1. **Prior to 25th May 2017**: shall remain valid until the expiry date indicated on the certificate;
2. **From 25th May 2017**: shall remain valid until the end of the period indicated on the certificate. They shall however become void at the latest on 26th May 2024 (4 years after the date of application of the Regulation 745).

The devices with a certificate that was issued in accordance to the previous points 1 and 2:

- May be placed on the market, or put into service, provided that **from the date of application of the new Regulation 745 (26th May 2020)** they continue to comply with the Directive and provided there are no significant changes in the design and in the intended use. However, the requirements of the new Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices, shall apply and replace the corresponding requirements in the Directive 93/42/CEE. So from May 2020, in the activities of periodical surveillance relative to certified MD still in accordance with old directive, also the requirements of the new Regulation related to the above-mentioned processes shall be assessed.
- May continue to be made available on the market or put into service until 26th May 2025 (after having communicated to Kiwa Cermet the number of lots manufactured until 26th May 2024).

When the above-mentioned certificates (points 1 and 2) expire, Kiwa Cermet will authorize the placing on the market or the putting into service of the MDs, for a period of maximum 1 year from the expiry date.

The certification related to the Directive, will become void by the above-mentioned terms. So, the manufacturers cannot use anymore the CE certification in accordance with the Directive and they cannot place into the market anymore the relative MDs if they exceed the above-mentioned expiry dates. For these cases, Kiwa Cermet will have to proceed with withdrawing the agreement and communicate the withdrawal of the certificate to the Ministry.

Your Kiwa Cermet reference personnel remains at your disposal for any further clarification. Yours Faithfully,

Alessia Frabetti
Business Sector Manager