Instruction to register the supply of alternative medical devices

A manufacturer, authorised representative, distributor, or importer can register the supply of an alternative medical device with the IGJ for medical equipment (class IIa/b and III) that do not carry a CE marking or that have not gone through the normal conformity assessment procedure.

An exception to this procedure is applicable for medical devices (like ventilators) and in-vitro diagnostics (tests) which are purchased via a central national working group initiated by the Ministry of VWS. Manufacturers and suppliers are requested to send specifications and information about the fulfilment of technical and clinical requirements to meldpunt@igj.nl. The inspection will forward the information to the relevant working group.

Registrations can be submitted by email to meldpunt@igj.nl while referencing "*Corona request care provider class II/III*". When doing so, the following information must be provided:

- Name and address details of manufacturer (including email address);
- date of request from care provider;
- particulars of care provider;
- name and type of medical device of which, according to the care provider, there is a shortage
- as a result of the coronavirus (including a statement from the care provider);
- name and type of medical device that can be delivered as an alternative;
- quantity of medical device to be delivered;
- overview of relevant standards;
- if present: specification of other relevant certificates;
- if present: status of CE conformity assessment procedure.

Depending on the information provided, the IGJ may carry out an additional assessment, additional information may be requested.

For supplying medical devices in class I, no notification has to be submitted beforehand to the IGJ. This temporary policy will remain in force as long as the coronavirus leads to shortages of medical equipment.