Subject: Consistency with EU law of the Italian registration requirement for medical devices bearing the CE mark

According to information supplied by a medical device manufacturer in southern Germany, the Italian authorities require detailed data to be provided about devices to be used in public hospitals in Italy, in accordance with the ‘classificazione nazionale dei dispositivi medici (CND)’ – national medical devices classification, even though these devices bear the CE mark and the information required can already be found in the corresponding German registers (those kept by the Deutsches Zentrum für medizinische Klassifikation (DZMK) – German Medical Classification Centre) and the Deutsches Institut für medizinische Dokumentation (DIMDI – German Medical Documentation Institute)).

The resulting double requirement to provide information and to register devices clearly creates substantial additional work and costs for non-Italian firms and is at odds with the requirement to accept the CE mark laid down in Article 4 of Directive 93/42/EEC concerning medical devices. It is also hampering the establishment of a barrier-free internal market.

Can the Commission state whether the approach taken by the Italian authorities is consistent with EU law, in particular the directive cited?

In addition, can the Commission clarify whether registration, subject to provision of the requisite information, in one Member State has legal force throughout the European market?

Are simplification measures (networking of national databases) planned in this context?

Are the Italian authorities acting lawfully in classifying and registering all medical devices, regardless of whether or not they meet European conformity requirements, on the basis of their own rules?

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