

Question for written answer E-015508/2015
to the Commission
Rule 130
Laura Ferrara (EFDD)

Subject: No CE certification test facilities for pacemakers in Italy - EU monitoring powers

Reference is made to the reply to written question E-008175/14 concerning irregularities and the virtual non-existence of a pacemaker testing laboratory, as reported on the news programme 'Report', available on:

<http://www.report.rai.it/dl/Report/puntata/ContentItem-6eed15c9-3e1e-48a8-b73e-c29565aef84f.html>.

The Italian National Institute of Health (ISS) is responsible for issuing certificates of conformity, to certify that pacemakers comply with the relevant EU legislation.

Nationally, it is the Ministry of Health that is supposed to ensure that the certifying body is functional and independent and that there is an absence of conflict.

Meanwhile, the EU may exercise its supervisory powers to check both compliance with legislation concerning testing and certification of conformity and the work done by the national authorities responsible for supervision.

In view of the above, and of the Commission's reply to the above-mentioned written question, can the Commission say:

1. whether the Italian authorities have provided answers to the Commission's questions;
2. whether, in exercising its supervisory powers, the Commission should not take action to check and monitor whether certificates of conformity are being properly issued in compliance with EU rules; namely whether it should not check and monitor those who are allegedly responsible for such supervision – in this case, the Italian Ministry of Health;
3. what measures it will take should the infringements be confirmed by the Italian authorities or by the outcome of the checks conducted by the Commission itself?