

Medical devices

2012/0266(COD) - 05/04/2017 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

A proposal to reject the Council proposal, submitted by the EFDD and ENF groups, was rejected in plenary by 66 votes to 635, with 2 abstentions.

In line with its recommendation for second reading by the Committee on the Environment, Public Health and Food Safety, Parliament approved, without amendment, the Council position at first reading.

The proposed Regulation seeks to establish rules to be complied with by medical devices and accessories to medical devices that are placed on the market or put into service in the Union for human use.

It replaces Council Directives 90/385/EEC and 93/42/EC which are no longer sufficient in regulating the sector.

Its objective is to enhance patient safety by: (i) introducing more stringent procedures for conformity assessments and post-marketing surveillance; (ii) requiring manufacturers to produce clinical safety data, performance and undesirable side-effects.