

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
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Automated external defibrillators (AEDs) including their pads/electrodes, are medical devices in the scope of Regulation (EU) 2017/745¹ (MDR). To be lawfully placed on the market in the EU, AEDs must comply with the safety and performance requirements of the MDR. This encompasses also the construction of devices and their interactions. Devices that are intended to be operated together with other devices or products, shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe². Connections to handle, such as electrical or mechanical coupling, must also be designed and constructed to minimise all possible risks, such as misconnections³.

To support compliance, the Commission requested the European standardisation organisations⁴ to develop a harmonised standard on safety performance of cardiac defibrillators⁵. This should take into account the different aspects related to design, functional compatibility, system performance, and reliability of AEDs.

Manufacturers must carry out appropriate post-market surveillance and vigilance activities on the devices they place on the market⁶. The competent authorities of the Member States for market surveillance are responsible to check and ensure that devices comply with the applicable requirements⁷, as well as for collecting relevant data.

¹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 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 (OJ L 117 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>).

² Section 14.5 of Annex I to the MDR.

³ Section 14.1 of Annex I to the MDR.

⁴ The European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC).

⁵ EN 60601-2-4:2011/prA2:2024 Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators: https://standards.cenelec.eu/orders/?p=CENELEC:110:::FSP_PROJECT,FSP_ORG_ID:78953,1257161&cs=11F05176BFE878336A43E526DB0A801EE.

⁶ Articles 83 to 92 of the MDR.

⁷ Articles 93 to 100 of the MDR.