fighting heart disease and stroke
european heart network

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Members‘ voice

Medical Device Regulation and its impact on children with congenital heart disease

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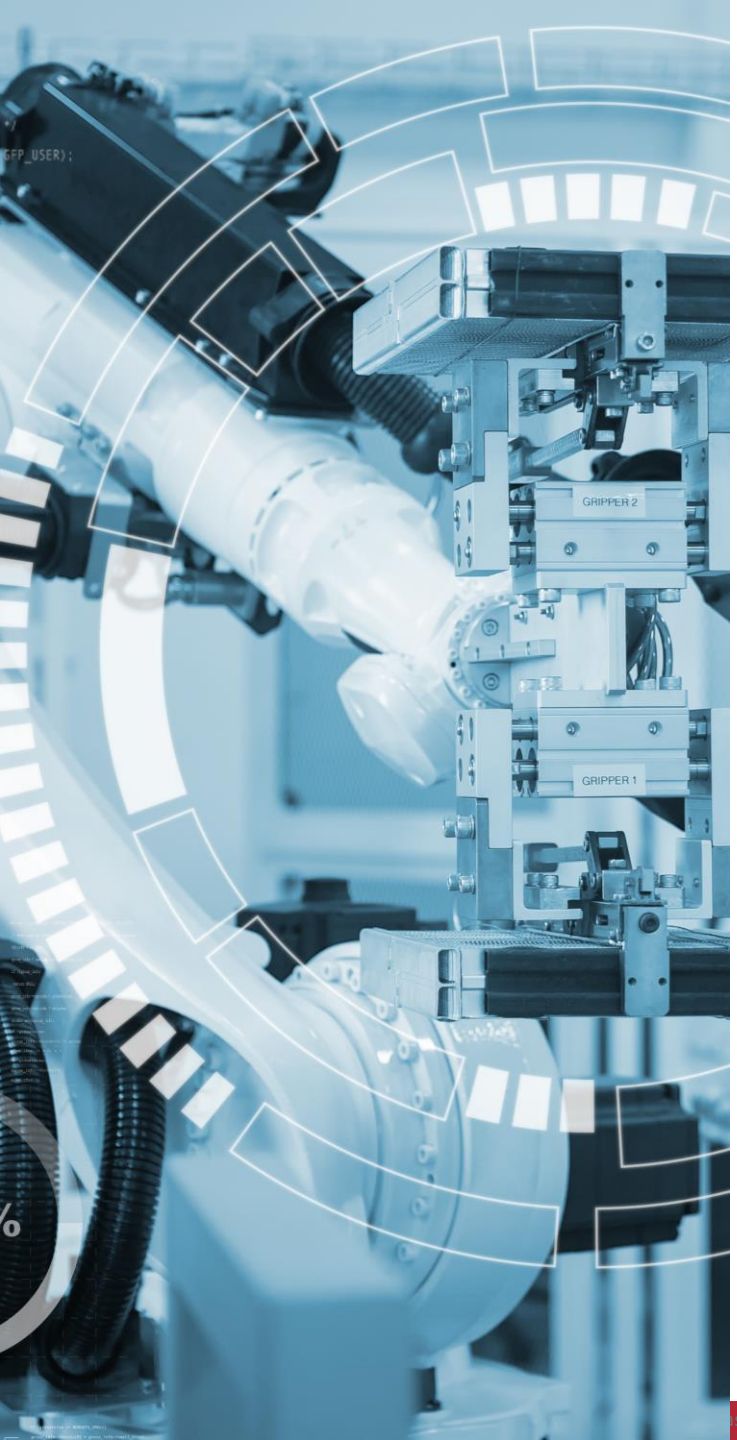
What has changed?

- Stricter monitoring obligations after placing medical devices on the market
- Further reporting and documentation obligations in the case of undesirable effects and malfunctions of medical devices
- Mandatory labelling of medical devices for manufacturers by means of Unique Device Identification (UDI)
- Registration in the EU database EUDAMED
- More extensive provisions for liability cases
- More complex certification procedures for manufacturers



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Manufacturers‘ position?

- Manufacturing numbers and profit are too low compared to administration.
- Recertification is either not possible for the manufacturer or not attractive enough.

(In Germany, pediatric cardiologists stated that more than 100 such products are at risk or have already vanished.)

Health Consequences?

- Devices for children and patients with orphan/rare diseases will disappear from the European market;
  → a significant shortage
- Babies, infants and children can‘t be treated with devices produced for adults.
- HCP have to choose other techniques with more risks, worse outcome or have no treatment option.

MDR as an excuse?

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- The question remains why so many products have already vanished from the market when manufacturers still have 3 years left to recertificate?
- Is the MDR an excuse to pull out of the market with products that are not highly profitable and blame the MDR?
- Is it the role of the European Commission or the national authorities to ensure that essential devices are available in the market?

In any case, it is the patient who will have to suffer the consequence and has to be protected.

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Your experiences?

- Have you experienced similar problems, or do you expect those problems in the future?
- Any feedback on action taken or future steps is highly appreciated:

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