

The European Union's Medical Device Regulation's Date of Application is May 26th 2021, when it will replace the Medical Device Directive (93/42/EEC).

DEFINITION OF ABBREVIATIONS

DoA:	Date of Application
DoC:	Declaration of Conformity
EU:	European Union

MD:	Manufacturer's Declaration
MDR:	Medical Device Regulation
OJEU:	Official Journal of the European Union

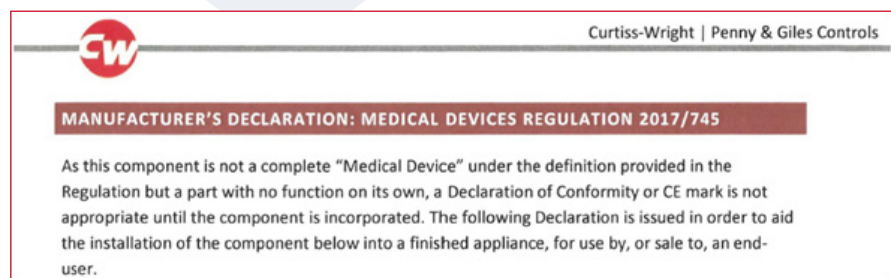
Support from Curtiss-Wright

As suppliers of components to Medical Devices, Curtiss-Wright are well-positioned to support our OEM customers and their supply chains in meeting the requirements of the MDR.

The basis of this support is to supply a Manufacturer's Declaration for each product type, which can be included in the overall documentation for the Medical Device to which the control system is fitted. This approach is necessary as, under the definition provided in the MDR, a control system is a part with no function of its own meaning it is a component of a Medical Device. Therefore, a Declaration of Conformity or CE Mark is not appropriate until the component is incorporated into the final product, i.e. a mobility vehicle.

As such, MDs are issued to aid the installation of the component (control system) into the finished product (mobility vehicle).

Curtiss-Wright can supply MDs for: **S-Drive**, **newVSI**, **(n)VR2** and **R-net**.



TÜV Certification

Although TÜV certification is not a requirement of the MDR, it does give assurances a product is designed and manufactured to the highest standards.



TÜV certificates are available for: **S-Drive**, **newVSI**, **(n)VR2** and **R-net**.



Note on MDR Annex 1

As of the DoA of the MDR, it will not state any mobility-vehicle-specific harmonized (cited in the OJEU) standards. To mitigate this, all CW control systems will be designed to comply with the latest versions of:

EN 10993-1
EN 14971

EN 12182
EN 62304

EN 12184

Obtaining Declarations and Certificates

Declarations and Certificates for all Curtiss-Wright mobility control systems can be downloaded here:

www.cw-industrialgroup.com/Products/Mobility-Vehicle-Solutions/Approvals