



Start

no

Do you market products under your name or trade name?

yes

Do you manufacture or fully refurbish medical devices or have another party do this for you?

yes

Manufacturer

yes / no

Are you established in the European Union and place a device from a third country (import) on the European Market?

yes

Importer

yes / no

Do you make medical devices available on the market (e.g. selling them) for which you are neither manufacturer nor importer and which you do not merely put into service?

yes

Distributor

yes / no

Do you have a written mandate from a manufacturer outside the European Union to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under Regulation (EU) 2017/745?

yes

Authorised representative

no

End