

21 July 2023

Ref: MA/MDPCD-001/2023

**Notice to Stakeholders –
Organisation Registration relevant to Medical Device Regulatory Sciences in Malta**

In line with Subsidiary Legislation 458.59 *Medical Devices and In Vitro Diagnostic Medical Devices Provision on the Maltese Market Regulation*, economic operators in Malta are obliged to register their organisation with the Malta Medicines Authority.

Kindly refer to the following link: <https://medicinesauthority.gov.mt/medicaldevices> for the relevant application form and guidance documents:

- MT-MDF02 *Application for Organisation Registration in relation to Medical Devices*
- GL-MDF02 *Guidance for Application for Organisation Registration in relation to Medical Devices*
- GL-MDF07 *Guidance of fees in relation to Medical Devices*

Your immediate cooperation to this matter is highly solicited.

Please ignore this Notice, if the organisation has been duly registered with the Authority.

Yours sincerely,

Medical Devices and Pharmaceutical Collaboration Directorate