

11 September 2023

Ref: MA/MDPCD-002/2023

**Notice to Stakeholders –  
Product Notification 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*, entities making available medical devices on the Maltese market are obliged to notify the marketed devices to the Malta Medicines Authority.

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

- MT-MDF05 *Application Form for Notification of Medical Devices Made Available on the Local Market*
- GL-MDF05 *Guidance for Application for Notification of Medical Devices Made Available on the Local Market*
- GL-MDF07 *Guidance of fees in relation to Medical Devices*

Your immediate cooperation to this matter is highly solicited.

Yours sincerely,

***Medical Devices and Pharmaceutical Collaboration Directorate***