For office use only: MDRP Registration Form received on: __ / __ / ____

MDRP Registration Form Reference No.: _____

MDRP Reference No.: _____

MT-MDF11

Application Form for Medical Device Registered Person (MDRP)

The application is valid when submitted with the relevant documents and fees.

Refer to the GL-MDS01 Guidance for Good Distribution Practice in relation to Medical Devices and GL-MDF07 Guidance on fees in relation to Medical Devices. Guidance documents and Application Form are available on the Malta Medicines Authority website: https://medicinesauthority.gov.mt/medicaldevices.

November 2024

Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000

info.medicinesauthority@gov.mt | (+356) 23 439 000

www.medicinesauthority.gov.mt

Section A.1 Applicant details

Surname:

Name:

Home address

Name/ No.:

Street:

Locality:

Country:

Post code:

Email address:

Telephone number:

Mobile number:

Section A.2 Application Type

☐ First application

☐ Revision of submitted details for MT-MDF11 Application Form for Medical Device Registered Person (MDRP)

☐ Amend MDRP details

☐ **Withdraw application for MDRP**

Application Reference:

Section B Eligibility Criteria

i) Citizenship - Tick as applicable, providing relevant documentation.

EU citizen

☐ Valid Passport/Identity Card document

Non-EU citizen

☐ Permanent Maltese residence

☐ Maltese Working Permit

ii) Qualifications/Experience

Experience and qualifications will be assessed from the Curriculum Vitae provided.

One of the following criteria related to qualifications / experience:

a. in possession of one of the following qualifications: a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by Malta, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one (1) year of professional experience in regulatory affairs or in quality management systems related to medical devices;

b. two (2) years of professional experience in regulatory affairs or in quality management systems related to medical devices.

iii) Medical Device Course certificate

Provide the name and certificate of the relevant course attended in relation to medical devices.

Section C Details of Payment

☐ Proof of Payment attached (Standard fee)

☐ Proof of Payment attached (Fast-track fee)

Section D Additional Documents

☐ Citizenship document/s

☐ Curriculum Vitae

☐ Medical Device Course certificate

☐ **Data Protection Consent Statement**

The applicant hereby consents to the processing of their personal data by the Malta Medicines Authority and understands that this data shall be processed in accordance with the General Data Protection Regulation (GDPR), Regulation 2016/679/EU of the European Parliament and of the Council of 27 April 2016, the Data Protection Act (Chapter 586 of the Laws of Malta) and the Malta Medicines Authority Data Protection Policy (P-MA05). The applicant also understands that the Malta Medicines Authority shall process this personal data in line with the purposes they are initially collected for. Exceptions to the latter include when the data subject consents to the new purpose, when there is a legal provision requiring or allowing the new processing or when the new purpose is deemed compatible with the purposes the personal data were initially collected for.

Consent for the publication of personal data on the Malta Medicines Authority website

As the regulatory Authority for Medical Devices the Malta Medicines Authority is the controller of your personal data as a Medical Device Registered Person, namely your name, address, email address, telephone number. The Malta Medicines Authority stores this information in accordance with applicable record retention requirements.

I, _____, holder of identity card/passport number _____ hereby consent to the publication of my email address on the Malta Medicines Authority website. I understand and agree that my email address will be made publicly accessible on the website for the purpose of facilitating communication between stakeholders.

I acknowledge that the publication of my email address is voluntary and that I have the right to withdraw this consent at any time by contacting the Medical Devices and Pharmaceutical Collaboration Directorate at Life Science Park, Sir Temi Żammit, San Ġwann 3000 or by phone and email at devices.medicinesauthority@gov.mt.

I understand that the Malta Medicines Authority will take all reasonable measures to protect my personal information in accordance with applicable data protection laws, including the General Data Protection Regulation (GDPR).

By signing this consent form, I confirm that I have read and understood the above information, and I freely give my consent to the publication of my name, surname and email address on the Malta Medicines Authority website.

Signature: _____

Date: _____

[Please fill out and return this form to authorise the publication of your email address on the MMA website.]

Malta Medicines Authority Declaration for Form Submission

I, the applicant, declare that all information given in the application form is true, complete and correct. I also bind myself to inform immediately any change to details in the application form and annexes, where relevant, to the Malta Medicines Authority.

Name & Surname:

Position:

Signature: _____

Date: