



For office use only:

Organisation Registration Form received on: __ / __ / ____

Organisation Registration Form Reference No.: _____

Organisation Reference No.: _____

MT-MDF02

Application Form for Organisation Registration in relation to Medical Devices

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

Refer to the *Guidance for Application for Organisation Registration in Relation to Medical Devices* and *Guidance on fees in relation to Medical Devices*. Guidance and Application Form are available on the Malta Medicines Authority website www.medicinesauthority.gov.mt.

November 2024

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SECTION A: APPLICATION INTRODUCTION

<p><i>A.1 Date of Application (dd/mm/yyyy):</i></p> <p><i>Applicant Name & Surname:</i></p> <p><i>Applicant Email Address:</i></p> <p><i>Applicant Contact Number:</i></p> <p><i>Applicant Type:</i></p>
<p><i>A.2 Type of Application (tick as applicable):</i></p> <p><input type="checkbox"/> First Application</p> <p><input type="checkbox"/> Change in Application details</p> <p><input type="checkbox"/> Withdraw Request</p> <p>Quote Organisation Registration No.</p>

SECTION B: ORGANISATION DETAILS

<p><i>B.1 Organisation Type (tick only one per application):</i></p>	
<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Importer
<input type="checkbox"/> Authorised Representative	<input type="checkbox"/> Distributor
<input type="checkbox"/> Notified Body	<input type="checkbox"/> Importer and Distributor
<p><i>B.2 Organisation Contact Details</i></p>	
<p>Organisation Name:</p>	<p>Organisation Telephone Number:</p>
<p>Organisation Address:</p>	<p>Organisation Email address:</p>
	<p>Organisation Type:</p>
	<p>Malta Business Register Number:</p> <p>_____</p>
<p>SRN number (except for Distributors and Notified Bodies):</p>	

B.3 MDRP/PRRC Contact Details	
MDRP/PRRC Contact Details	
Contact Name *:	Job Title*:
Contact Email address*:	Contact Telephone Number*:
MDRP registration number (if applicable):	
If more than one MDRP/PRRC kindly indicate.	
<p>*If applicant is a Manufacturer or Authorised Representative complete with details of PRRC.</p> <p>*If applicant is a Distributor or Importer complete with details of MDRP.</p>	

SECTION C: DETAILS OF PAYMENT

- ☐ Standard
- ☐ Fast Track
- ☐ Proof of Payment attached

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, repealing Directive 95/46 EC, 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.*

Additional documentation

I have attached a copy of the Malta Business Registry Certificate of Company Registration. ☐

I have attached a copy of the ID card of the representative person of the organisation. ☐

I have attached official documentation for the Medical Device Registered Person. ☐

For Authorised Representatives: I have provided evidence by attaching a notarised copy of the mandate as per MDR Article 11(3). ☐

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.

Company Name (if applicable):

Name & Surname:

Position:

Signature:

Date: