A Checklist to Prepare for EUDAMED Actor Module Registration

Step 1: Actor Identification — Complete ☐ Incomplete ☐

Name of the Organisation:

Address:

City:

Country:

VAT:

EORI:

Step 2: Organisation Identification document to be uploaded — available ☐ or unavailable ☐

Step 3: Decide actor registration role:

Manufacturer ☐ Authorised Representative ☐ System/procedure pack producer ☐ Importer ☐

Step 4: Authorised Representative details (required only if you are a non-EU Manufacturer):

Name:

Address:

City:

Country:

SRN:

Note: For Non-EU Manufacturer, SRN of Authorized Representative is required to complete the actor registration process. Therefore, the Authorized Representative must register on EUDAMED to obtain the SRN and provide the same to the Non-EU Manufacturer.

Step 5: Is the EUDAMED Mandate Summary document that a non-EU manufacturer needs to upload

available ☐ or unavailable ☐

Mandate Document Format available at: https://ec.europa.eu/health/sites/health/files/md_eudamed/docs/md_mandate_summary_en.pdf

Step 6: Do you know mandate document start date: MM-DD-YYYY end date: MM-DD-YYYY (N/A if unavailable)

Step 7: Actor's public contact details — available ☐ or unavailable ☐

email:

Telephone:

Website:

Details will be visible to the public on EUDAMED Data Base: https://ec.europa.eu/tools/eudamed/#/screen/home

Step 8: Person Responsible for Regulatory Compliance (PRRC):

i. Person Responsible for Regulatory Compliance (PRRC) appointed: Yes ☐ No ☐

ii. PRRC appointment document or letter — available ☐ or unavailable ☐

iii. Do you intend to have more than one PRRC: Yes ☐ No ☐

Step 9: Person Responsible for Regulatory Compliance (PRRC) details:

Name:

Address:

email:

Telephone:

If Step 8 (iii) is yes, then fill Step 9 the same number of times.

Step 10: Confirm the details of the Local Actor Administrator (LAA) as given below:

EU Login data:

Name: _____ email: _____

EUDAMED data:

Name: _____ email: _____

Note: The person, who first enters the details of an actor in EUDAMED, automatically becomes the LAA.

Step 11: Is LAA is a Subcontractor? Yes ☐ No ☐

In case step 11 is yes, Furnish details as required below:

Name:

Address:

email:

Telephone:

Step 12: Is the Declaration on Information Security available? Yes ☐ No ☐

Signed Declaration on Information Security has to be uploaded at EUDAMED.

Format available at: https://ec.europa.eu/health/sites/health/files/md_eudamed/docs/md_declaration_actor_registration_en.pdf

Step 13: Competent Authority details Complete ☐ Incomplete ☐

Name:

Address:

Country:

email:

Telephone:

Note: If you are a non-EU Manufacturer, competent authority details will be displayed on the screen. In other cases, competent authority is required to be selected by you (if it is not already pre-completed). The Competent Authority will validate the registration request and issue the SRN.

Step 14: The above steps are fulfilled, What next?

Get set go!

Sign in/ create the EU log in account on EUDAMED: https://webgate.ec.europa.eu/eudamed
Select Actor registrations popped up on User & Actor Registration page & proceed further.

For further queries or support, please contact: marketing@compliancequest.com

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About ComplianceQuest

ComplianceQuest is the fastest growing, 100% modern cloud **Next Generation Enterprise Quality and Safety Management System (QHSE)** natively built and run on the **Salesforce platform**. Our unified Next Generation QHSE solutions help our customers of all sizes deliver quality products and services in the safest, most sustainable way by mitigating risk, problems, and inefficiencies while protecting customers, employees, suppliers and brand.

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