



Eudamed

WG meeting

Brussels, 14th November 2012



Contents

Improvements & Business rule changes
Current Operations/Future Developments



European
Commission

Improvements & Business Rule Changes

Health and
Consumers



European
Commission

Create CIV

Creation/ Existing Criteria

Manufacturer name:	<input type="text" value="255 Chars"/>	<input type="text" value="120 Chars"/>
CIV title:	<input type="text" value="1000 Chars"/>	<input type="text" value="4000 Chars"/>
		Primary objective(s):

Protocole code:

Field sizes
fixed and
extended



European
Commission

CIV Addition



Clinical Investigation Details ()

Main CIV Actors Devices CA Information CA Decision Comments Attachments

Owner: BE-CA-999

Reference: + Version: 1

CA Reference:

Status: Requested Date:  



Status Comment:

Protocol Code:

Title:

Submission Type: Select

Primary objective:

Submission Date:  

Leading CA:

New for
leading CA

Device IVD Change

Main	Actors	IVD	Marketed in	Comments	Certificates	Attachments
New:		<input type="radio"/> Yes	<input checked="" type="radio"/> No			
Conformity with Common Technical Specifications:		<input type="radio"/> Yes	<input checked="" type="radio"/> No	<input type="radio"/> NA		
Outcome of Performance Evaluation:		<input type="radio"/> Yes, attached	<input type="radio"/> Yes, on request	<input type="radio"/> No	<input type="radio"/> NA	

New IVD Options



European
Commission

NCAR Addition

New optional field →

Confidential:	<input type="radio"/> Yes <input type="radio"/> No
Complete investigation:	<input type="radio"/> Yes <input type="radio"/> No
Candidate leading CA:	<input type="text" value="No"/>
CA contact:	<input type="text"/>
Manufacturer Ref/FSCA:	<input type="text"/>
Manufacturer contact:	<input type="text"/>
Authorised Representative contact:	<input type="text"/>
Outcome:	<input type="text" value="Select"/>

Certificate Types

Main | Actors | Scope of certificate | Comments | Devices | Attachments

Owner: BE-CA-999

Reference:

CA Reference:

Version: 1

Status: Issued

Status Comment: Compliance: unapproved substantial changes

Certificate Number:

Certificate Type: Directive 93/42/EEC Annex IV

Date of Issue:

Expiration Date:

Optional for certificate type



European
Commission

Certificate Status

Certificate Details () Please correct the errors! All tabs need to be checked!

Main | **Actors** | **Scope of certificate** | **Comments** | **Devices** | **Attachments**

Owner: BE-CA-999 **Date of Issue:**

Reference: **Expiration Date:**

CA Reference:

Version: 1

Status: **Refused** **Date:** ← ←

Status Comment: **Compliance: unapproved substantial changes** ← ←

Certificate Number:

Certificate Type: **Directive 93/42/EEC Annex IV**

Mandatory for
status refused

Select Options Edited

Select

- Early termination on safety grounds
- Halted
- Refused
- Significantly modified
- Temporarily interrupted

CI Status

Requested

- Clock Stopped
- Completed
- Interrupted
- Ongoing
- Requested

CI Decisions

NCAR
Attachments

Type

Select

- Batch numbers
- Serial numbers
- Periodic Summary Report
- Trend Report
- Other

Device
Attachments

Type

Outcome of Performance Evaluation

XSD Changes

Increasing field sizes

Corrected out of sync field sizes

Adding new fields e.g. Leading CA

Uploads Since XSD Change

Devices	1637
Certificates	47
Actors	1890
Incidents	25
Clinical Investigations	30

Between September 10th and November 5th 2012



European
Commission

Ongoing XSD Improvements

News Message

New functionalities: Eudamed release 4.4 - Updated XSD's

[Eudamed-CI2.xsd](#) (Updated 31 October 2012)

[Eudamed-v7.xsd](#) (Updated 31 October 2012)

Last updated



European
Commission

Current Operations/Future Developments

Health and
Consumers

Planned items

Country restrictions - Authorised Representatives.

Certificate Status Date in the future.

Unknown Eudamed ID.

Corrections to NCAR PDF's.

Actor tab under Devices fails to show contacts.

Corrupt PDF's on download.



European
Commission

Eudamed Privacy Statement

Eudamed Privacy Statment ✕

Please read, then accept or reject the Eudamed privacy statement.

Click to read the Eudamed privacy statement

[Accept](#) [Reject](#)



European
Commission

Thank you.

Health and
Consumers