**EURS** ⟩ validator

**EXTEDO**
eRegulatory Affairs

Product Information

# EURSvalidator™

## The trusted technology for eCTD and NeeS compliance

Trusted by regulatory authorities across the world, including the European Medicines Agency (EMA), EURSvalidator is designed to ensure eCTD and NeeS compliance.

### Benefits

⟩ Trusted technology: 80 % of regulatory authorities in Europe use EXTEDO validation technology (EURS) for ensuring eCTD and NeeS compliance.
⟩ Flexible: Multiple subscription options for individual validation requirements
⟩ Up-to-date: Latest validation sets provided in timely manner
⟩ One tool: Integrated validation sets on a global scale
⟩ Expertise: EXTEDO is the consulting partner of choice for more than 35 regulatory authorities worldwide – Profit on the back of our success!

EXTEDO's EURSvalidator provides multiple subscription options for individual validation requirements and enables users to configure their EURSvalidator subscription according to the country or region they want to file the submission. The validator enables users to combine different validation set packages within one subscription.

EXTEDO cooperates closely with regulatory authorities in order to guarantee that the relevant validation sets are included in the respective subscription packages and validation sets are up-to-date.

As the consulting partner of choice for more than 35 regulatory authorities worldwide, we ensure the greatest possible accuracy in managing your medicinal or veterinary eSubmissions.

| Result: | ✖ | Invalid |
|---|---|---|
| Submission: | | Product ABC |
| Sequence: | | 0008 |
| MD5: | | 530659857d0773a496e18b7c846f388b |
| Validation Start: | | 19.08.2015 21:09 |
| Validation Time: | | 0 s |

**File Level Tests**

| Total: | | 14 files |
|---|---|---|
| Valid: | | 7 files |
| Valid with Minor Issues: | | 5 files |
| Invalid: | | 2 files |
| Skipped: | | 0 files |

**Submission Level Tests**

| Failed: | | 1 tests |
|---|---|---|

**Severities**

| Error | 3 tests |
|---|---|
| Warning | 6 tests |
| Success | 2 tests |

Validation result of a submission sequence

| ProductXYZ | 0001 | ✖ | EU-eCTD v5.0 (DTD 2.0) | ▾ | Validation finished. |
|---|---|---|---|---|---|
| Product zyx | 0000 | ✖ | EU-eCTD v4.1 (DTD 1.4) | ▾ | Validation finished. |
| Product zyx | 0001 | ✔ | EU-eCTD v4.1 (DTD 1.4) | ▾ | Validation finished. |
| Product ABC | 0000 | ✔ | EU-eCTD v2.1 (DTD 1.3) | ▾ | Validation finished. |
| Product ABC | 0001 | ✔ | EU-eCTD v2.1 (DTD 1.3) | ▾ | Validation finished. |
| Product ABC | 0002 | ✔ | EU-eCTD v2.1 (DTD 1.3) | ▾ | Validation finished. |
| Product ABC | 0003 | ✔ | EU-eCTD v2.1 (DTD 1.3) | ▾ | Validation finished. |
| Product ABC | 0004 | ▷ | EU-eCTD v2.1 (DTD 1.3) | ▾ | |
| Product ABC | 0005 | ▷ | EU-eCTD v2.1 (DTD 1.3) | ▾ | |
| Product ABC | 0006 | ▷ | EU-eCTD v2.1 (DTD 1.3) | ▾ | |
| Product ABC | 0007 | ▷ | EU-eCTD v4.1 (DTD 1.4) | ▾ | |
| Product ABC | 0008 | ✖ | EU-eCTD v4.1 (DTD 1.4) | ▾ | Validation finished. |
| Product ABC | 0009 | ▷ | EU-eCTD v4.1 (DTD 1.4) | ▾ | |
| Product ABC | 0010 | ▷ | EU-eCTD v4.1 (DTD 1.4) | ▾ | |
| Product ABC | 0011 | ▷ | EU-eCTD v4.1 (DTD 1.4) | ▾ | |

Overview of the validated sequences

## Functional Overview

⟩ **Turn on/off validation sets** – In the Options dialog box the user can select or deselect validation sets to be enabled or disabled respectively. By default, all available validation sets are displayed.

⟩ **Validation set/DTD Autoselector** – EURSvalidator detects and selects the applicable validation sets automatically (not available for NeeS submissions!). If one or more applicable validation sets were found, EURSvalidator chooses the current validation standard automatically. However, the user still may select one of the detected validation set manually from the Validation Set drop-down list. After the initial installation, the newest versions of the validation sets are selected by default. Users may change these defaults according to their requirements. These settings will be preserved after upgrades or re-installation of the software. If desired, a user may always revert to the default selection.

⟩ **Validate multiple submissions** – User can start the validation for all pending submissions in the Submission Explorer simultaneously. All pending submissions that have not been validated yet will be validated simultaneously.

⟩ **Validate multiple dossiers** – User can start the validation for all pending dossiers in the Submission Explorer simultaneously. All pending dossiers that have not been validated yet will be validated simultaneously.

⟩ **Display envelope information in the envelope tab page** – Envelope attributes of the submission that is currently selected in the Submission Explorer, is displayed in the Envelope Tab Page of the Information Explorer.

⟩ **Envelope Viewing** – Display of envelopes in the Submission Explorer according to country selection.

⟩ **PDF Reporting (short+long)** – After performing the validation process the user can generate a report for validation results of a selected submission. Reports are generated in PDF format and can be opened, viewed, and printed with any PDF reader program. There are multiple types of report: Short Report: This standard report type contains detected errors only. Long Report: The long report contains detected errors and additionally, warnings, and detailed information.

⟩ **Report auto-save** – EURSvalidator allows saving a summary or a detailed validation report in the dossier folder automatically.

⟩ **Report Mail service** – EURSvalidator allows sending out a summary or a detailed validation report directly out of EURSvalidator, using your default mail client.

EURSvalidator uses a regional subscription model with packages of validation sets available depending on the country or region you want to file your submission within. Different validation set packages can be combined within one subscription.

EXTEDO cooperates closely with regulatory authorities. We guarantee that all relevant validation sets are included in the respective subscription package and validation sets are always up-to-date.

## Available Modules

EURSvalidator uses a regional subscription model with packages of validation sets available depending on the country or region you want to file your submission within. Different validation set packages can be combined within one subscription. Modules for the following regions are available:

**EU North**
(Sweden, Norway, Denmark, Finland, Iceland)

**EU West**
(France, Belgium, Netherlands, Luxembourg)

**EU Central**
(Germany, Austria, Liechtenstein)

**EU South**
(Spain, Portugal, Italy, Malta, Greece, Croatia, Slovenia, Cyprus)

**EU East**
(Poland, Czech Republic, Slovakia, Hungary, Estonia, Latvia, Lithuania, Bulgaria, Romania)

**EU UK & Ireland**
(United Kingdom, Ireland)

**Switzerland**
(Switzerland (without eDok))

**North America**
(USA, Canada)

**Asia Pacific**
(all member countries of the Gulf Cooperation Council (GCC), Australia, Jordan, Japan, Thailand, Taiwan)

**South Africa**
(South Africa)

**Global**
(all available validation sets)

**EU Unlimited**
(all EEA countries and EMA, all procedure types)

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# For further information contact your local EXTEDO representative:

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**About us**

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes and are the only vendor that provides solutions covering the entire regulatory landscape. Today, EXTEDO enables more than 35 regulatory authorities and over 1000 maintained customers across 65 countries to deliver Effortless Compliance™.

**Microsoft Partner**
Gold Application Development