

 **Seelva Version 1.0****FACTORY RELEASE FORM**

Seelva software provides calculations and reports dedicated to Analytical Validation.

This is a product of:



Rue de l'Hôpital 1, CHU Bat B36 - 4000 LIEGE 1 (Belgium)

Product Quality was managed by Arlenda

An **Installation Qualification** demonstrated that Seelva environment can be installed as described in the installation document (**SEELVA-10**) and that the server is able to satisfy Seelva performance specifications.

An **Operational Qualification** was done using the validation environment on 7 "Release candidate" versions: **Seelva V1.0 RC1, Seelva V1.0 RC2, Seelva V1.0 RC3, Seelva V1.0 RC4, Seelva V1.0 RC5, Seelva V1.0 RC6 and Seelva V1.0 RC7.**

During these tests,

- 10 high incidents were detected and closed
- 5 medium incidents were detected and closed
- 35 low incidents were detected and 26 of them are closed

The 9 remaining low incidents have no impact on the quality of the results and on their validity (additional information in the Validation Report, **SEELVA-31**).



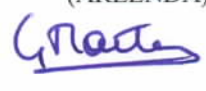
A **Performance Qualification** was done using the production environment, on version: **Seelva V 1.0 PROD.**

During this test,

- 1 medium incident was detected and closed

A **Performance Qualification** was done using the production environment, on version: **Seelva V1.0a PROD.** This last Qualification demonstrated that the complete process of **Seelva** (calculation, reporting, and environment) works well in its specified operating environment. Standard Operating Procedures were checked to ensure change control management and traceability, and availability of an up to date user's guide was also verified.

All these qualification results enable the Validation Committee to ensure that **Seelva V1.0a PROD can be released.**

<p>Mark DENHAM Quality Assurance Associate (ARLEND A)</p>  <p>07-APR-2011</p>	<p>François MOONEN Product Project Manager (ARLEND A)</p>  <p>07 - APR - 2011</p>	<p>Gaëlle MARTIN Quality Assurance Manager (ARLEND A)</p>  <p>07 . APR . 2011</p>
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