



<b>FACTORY RELEASE FORM</b>
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**e.noval** software provides calculations and reports dedicated to Analytical Validation.

This is a product of:

**ARLEND**

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

Quality Product was managed by Qualilab and Arlenda (creation of a Validation Committee):

**QUALILAB**

*1121, Rue de la Bergeresse - 45160 OLIVET (France)*

An **Installation Qualification** demonstrated that e.noval environment can be installed as described in the installation document (*ENOV3.0-15*) and that the server is able to satisfy e.noval performance specifications.

An **Operational qualification** was done using the validation environment, on 5 "Release candidate" versions: **e.noval V 3.0 RC1**, **e.noval V 3.0 RC2**, **e.noval V 3.0 RC3**, **e.noval V 3.0 RC4**, and **e.noval V 3.0 RC5**.


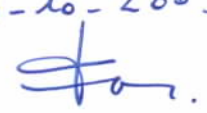
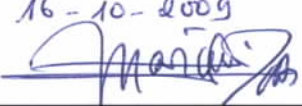
During these tests,

- 8 high incidents were detected and closed
- 5 medium incidents were detected and closed
- 26 low incidents were detected and 22 of them are closed

The 4 remaining low incidents have no impact on the quality of the results and on their validity (additional information in user's guide).

A **Performance Qualification** was done using the production environment, on version: **e.noval V 3.0 PROD**. This last Qualification demonstrated that the complete process of **e.noval** (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 **e.noval V 3.0 PROD** can be released.

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