E-marking software certificate

Number **ES8971** revision 0
Project number 2433985

Issued by NMi Certin B.V.

In accordance with WELMEC 6.4 Issue 1, Annex 2 and requirements of clause 4 of Description ES8971 revision 0.

Applicant

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Software

Suitable to evaluate e-marked pre-packages

Brand	:	Systec
Designation	:	SQC E in combination with PC SQC

Further properties are described in the annex:
- Description ES8971 revision 0.

An overview of performed tests is given in the annex:
- Description ES8971 revision 0.

Issuing Authority

NMi Certin B.V.
2 March 2021

Certification Board

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Description

1 General information about the e-marking software

All properties of the e-marking software, whether mentioned or not, may not be in conflict with WELMEC 6.4 Issue 1, Annex 2 and requirements of clause 4 of this Description.

This certificate is the positive result of an evaluation of software that:
- uses measuring results of a legal measuring instrument (Directive 76/211/EEC, Annex I,4),
- automatically accepts and rejects, or separates in classes,
- presents the results of the calculations, the number of acceptable and unacceptable prepackages,in such a way that a packer can decide on the acceptance and rejection of (batches of) e-marked prepackages.

1.1 Essential characteristics

Formulas:

- Average of all batch package weights: $\overline{x} = \frac{\sum_{i=1}^{n} x_i}{n}$

- Standard deviation (sampling): $s = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \overline{x})^2}{n-1}}$

1.1.1 PC SQC software

The e-marking software 'PC SQC' runs as a service on a computer and has the primary purpose of storing (without modification) of e-mark reports in a database of such as those offered by automatic checkweighers or non-automatic weighing instruments (for 100% control or for sampling).
The 'PC SQC' software can access the database. By using this software, it is possible to retrieve the stored e-mark reports. A selected e-mark report is displayed if desired, exported to a PDF file.

Operating system for the 'PC SQC' software:
- Windows.

Relevant functions:
- Additional functions to facilitate trade and management;
- Interface for receiving e-mark reports;
- Storage of reports in a secured database. The protection is performed by calculating a checksum of the report and storing this together with the report in the database;
- Look up and presentation or printing of the reports.

Software identification:
- The certificate number (ES8971) and the software version number 3.x.x.x is shown continuously in the title bar of the operator window of the PC SQC software.
- The full checksum is 1316e1c7ae26c3911b3086816d48fbf76d801ea6a6a7c55851d5733fd5f3436c, from which the last 6 digits are displayed: f3436c

Software protection :
- The software is placed on the hard disk or eprom(s) in executable file(s);
- The software operates with protected software interfaces;
- The software is protected against intentional and unintentional changes by a checksum;
- The software will not operate if the legally relevant software has been tampered with;
- Audit trail for changes in the configuration.

1.1.2 SQC E software NAWI (Sampling station)

The e-marking software 'SQC E' is installed on a NAWI sampling station mentioned in 1.2;
All calculations are carried out on a NAWI mentioned in 1.2;
The e-marking software can be used in two configurations:
- Stand-alone on a NAWI. In this situation the maximum number of batch reports that can be retained locally on the NAWI is 2500 with 250 products. When this number is reached and no offload to a server over network connection is possible the instrument stops working until such a time that the batch reports (or part thereof) are printed and/or saved;
- On a NAWI in combination with central registration and presentation software 'PC SQC' which runs on a separate computer system. Communication is established via network connection and uses proprietary communication protocols.

The 'SQC E' software is embedded in the indicator.

Relevant functions:
- Net calculation from gross weight and preset tare;
- Product definition;
- Additional functions to facilitate trade and management;
- Interface for sending e-mark reports to 'PC SQC' software;
- Storage of reports in a secured database. The protection is performed by calculating a checksum of the report and storing this together with the report in the database;
- Look up and presentation or printing of the reports.

The software will show the following information:
Press the Alt- and Zero-setting key simultaneously to enter the Master Mode. Go to sub-group E marked. Press Enter to step through the information:
- Name of the producer;
- This certificate number ES8971;
- Checksum / Version: ID:15487782/V4.xx.yy

Software protection :
- The software is placed on the hard disk, eprom(s) in executable file(s);
- The software operates with protected software interfaces;
- The software is protected against intentional and unintentional changes by a checksum;
- The software will not operate if the legally relevant software has been tampered with;
- The user is prevented from accessing the operating system;
- Audit trail for changes in the configuration.

1.1.3 General software information

Data	Used for sampling	Presented in print-outs*
Product	√	√
Product name	√	√
Machine	√	√
Batch ID	√	√
Characteristic	√	√
Weighing station	√	√
Operator	√	√
Date/ time	√	√
Nominal value	√	√
Limits (TU_1 / TU_2)	√	√
n (sample size)	√	√
Target weight (nominal + supplement)	√	√
Average value	√	√
Average difference from the nominal weight in g and %	√	√
Standard deviation	√	√
Preset tare	√	√
Minimum	√	√
Maximum	√	√
Density	√	√
Number of packages rejected or separated in classes	√	√
Summation of sample tests	√	√

* print-outs are statistics based on hourly, daily, weekly, yearly period, or on manual command

1.2 Conditional parts

NAWI based on:

Producer	Type	Certificate number
Systec	IT6000E or IT8000E	TC8477

The e-marking software works in combination with:
- SQL database that can work with the e-marking software;
- Suitable web server;
- Non-automatic weighing instrument with an EC type-approval certificate or a EU-type examination certificate based on TC8477.

1.3 Non-essential parts

The e-marking software may be connected to non-essential devices, for example but not limited to bar code readers, foot switches, secondary displays and cash drawers, provided that:
- They do not present primary data used for purposes mentioned in Article 1(2), (a) to (f) of Directive 2014/31/EU unless the "Preliminary observation" in Annex I of the Directive is satisfied;
- They do not lead to an instrument having other conditional characteristics than those fixed by this certificate.

2 Seals

The software uses software sealing. No hardware sealing is required.

3 Reports

An overview of performed tests is given in the reports:
- No. NMi-2433985-01 dated 2 March 2021 that includes 27 pages.

A report can be a test report, an evaluation report, a type evaluation report and/or a pattern evaluation report.

4 Additional requirements

In addition to WELMEC 6.4 Issue 1, Annex 2 the following requirements are valid for the e-marking software:
- The records of each batch (hour production or less) shall be stored. If the software is capable of indicating the exceeding of a rejection limit, this shall be visible on these records;
- The set points (target setting, limits, tare, density, acceptable percentage of TU_1 etc) of the measuring instrument must be kept in relation to the records of the batches;
- When the product changes, the set points must be stored together with the records of the batches. After that, registers must be cleared. Records may only be cleared after they are stored;
- The correct unit shall be behind the measuring results separated by one space;
- It must be possible to reproduce/show the records that were available for the packer on a certain moment in time (on screen or printed);
- An instruction to adjust the filling machine that is based on sampling results may not lead to deliberate under filling.
- All measuring results within a range of 25% below and above the nominal quantity account for a plausible quantity and must not be rejected by the software as a 'out-of-the ordinary' value. They must be accepted as normal value by the software.
- An automated system based on (a) non-automatic weighing instrument(s) (NAWI) may only accept a new measuring result after the NAWI has been unloaded to a value less that Min.
- In case of automatic weighing instruments, monitoring the average quantity of product per hour can be part of the system;
  Each version of the e-marking software must be identified with a special and unique code which must be easily accessible.