Report of Validation

Compliance Package

COMPLIANCE PACKAGE

Always compliant – always safe.

Directive-compliant production in the food industry

Food safety is a key aspect of the global food industry. Delivery of defective products may cause unpleasant consequences for the manufacturer. It can lead to expensive recalls or recourse claims and have a negative impact on the company's image. We would like to relieve you of this concern and support you in finding the best possible approach to ensure food safety. Our Sesotec high-end devices detect quickly and reliably a wide variety of foreign bodies in food. But that's not all: Some of our new devices also feature the **Compliance Package**, the innovative software for seamless and efficient documentation which guarantees the production of foodstuffs in compliance with the guidelines.

Compliance Package

For the greatest possible detection accuracy

We attach the greatest importance to ensuring that our inspection systems function reliably and make certain of this with the help of our 6-step approach to quality control. This ranges from advice on the selection of the right device to its functional testing on the basis of test bodies in actual production operation, in addition to annual maintenance which includes the issuance of a certificate.

Routine performance monitoring with the Audit Check.
In addition, operator validation (monthly or quarterly routine) with IVP.

	Sesotec Pre-Validation						
Sesotec Qualification	Sesotec Validation	Annual Sesotec manufacturer validation and maintenance				Sesotec Re-Validation	Annual Sesotec manufacturer validation and maintenance
		Year 1	Year 2	Year 3	Year 4		

Qualification	Installation	Operation	Significant Changes

Your worries ...

For you, as a food manufacturer, product quality is a top priority. In addition, you are required by law to comply with a whole range of food standards. It is a big responsibility, as the slightest mistake would not only cost you dearly, but also damage your image considerably. Product recalls, claims for damages and consumer losses are just some of the possible consequences of faulty products.

... our solution!

We would like to make sure that you sleep peacefully at night and with our Sesotec Compliance Package, we have developed an all-round carefree system for food safety. With this we guarantee you not only a rule-compliant production of foodstuffs, but also that you will benefit from process reliability during the introduction of new products, knowing that your machines are always working flawlessly and reduce product waste. Moreover, thanks to the paperless documentation in the machine you are optimally protected from tampering.

Qualification

Ensuring that the correct device/system is selected for the detection of foreign bodies and thus the hazards from the HACCP analysis are neutralized.
The qualification at Sesotec includes the verification of the detection accuracy (P.O.D.) for all available foreign body types (10/10 detection passes).
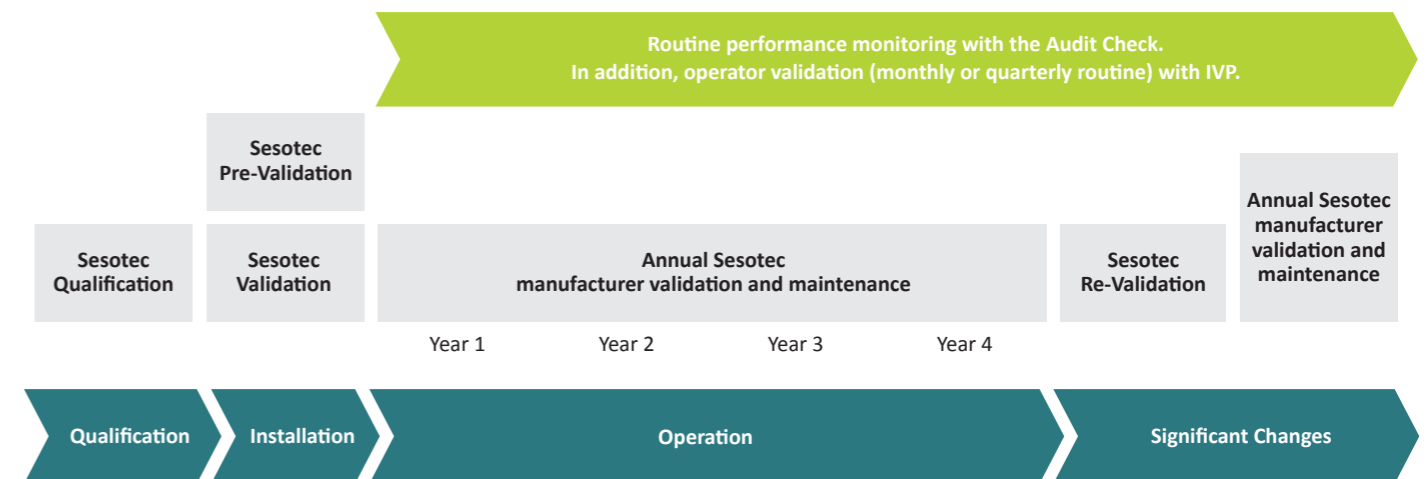
Pre-Validation

Commissioning of the device by Sesotec without Production conditions. Determination of the recognition accuracy for all available foreign body types with the help of existing products (at least 10/10 runs per foreign body type and product group) and determine the expected false ejection rate (F.R.R.).

Validation / Re-Validation

First confirmation of the F.R.R. as well as the P.O.D. under production conditions for all available foreign body types (at least 10/10 passes for each foreign body type and each product group) or re-validation of the detection accuracy and false reject rate after a substantial change in the production line by Sesotec.

Monitoring

Daily / Hourly check of operational readiness of the inspection system before start of production or after product change. Testing the device with at least one detection / rejection run of a test body. The regular review takes place via the audit check by the operator.

Operator Validation

In conjunction with the IVP software, the operator also carries out validations at regular intervals (monthly / quarterly), validate further products and document it in the „Report of Validation" and save it to the device.

Manufacturer Validation

Checking the electrical properties as well as the safety of the device and creation of a validation certificate (including confirmation of the F.R.R. and the P.O.D.) and a service report by Sesotec. The manufacturer validation should be done annually.

The Compliance Package

Food safety knows no compromise. Our software for seamless and efficient documentation in food production – consisting of the functions Audit-Check, Sensitivity Prediction, Compliance Mode, Integrated Compliance Monitoring, and Integrated Validation Process – is available for the VARICON+ IC, the LIQUISCAN VF IC, the RAYCON D+ HX as well as RAYCON D+ HX LW.

The five components of the Sesotec Compliance Package

	Audit-Check	Sensitivity Prediction	Compliance Mode	Integrated Compliance Monitoring – ICM	Integrated Validation Process – IVP
VARICON+ IC	INTEGRATED	INTEGRATED	INTEGRATED	OPTIONAL	OPTIONAL
LIQUISCAN VF IC	INTEGRATED	INTEGRATED	INTEGRATED	OPTIONAL	OPTIONAL
RAYCON D+ HX	INTEGRATED	OPTIONAL	INTEGRATED	OPTIONAL	OPTIONAL

Perfectly combined:
Sesotec machines and the compliance package

VARICON+ IC

The integrated metal detector INTUITY reliably detects magnetic and non-magnetic metal contaminants in packaged, unpackaged, and loose food. Thanks to multi-simultaneous frequency technology and digital signal evaluation, the INTUITY guarantees the best detection performance – also for food with a high product effect.

LIQUISCAN VF IC

The LIQUISCAN VF with INTUITY Control reliably detects and separates magnetic and non-magnetic metal impurities in liquid or pasty products in pumping lines. It was specially developed for use in industries with high hygienic requirements and can be flexibly integrated into any production line.

RAYCON D+ HX

RAYCON D+ HX and RAYCON D+ HX LW are high-precision X-ray inspection systems, which were specially developed for use in the food industry. The systems quickly and reliably recognize various foreign bodies in packaged as well as unpackaged food – regardless of their size, shape, or position. The devices can be installed in the middle of the production line as well as for the final inspection of packaged food.
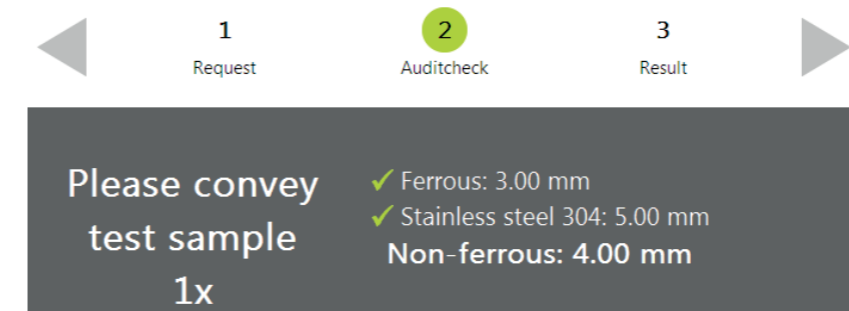
Higher Level Compliance Package

With Sesotec machines you are on the safe side as far as international food standards are concerned. As standard, the machines also meet the quality requirements of Marks & Spencer.

Audit-Check

Quality assurance 4.0: With the help of a process wizard, the Audit-Check leads through the audit routine and logs all steps. This continuous quality monitoring is of enormous importance, especially for food producers and processors, to ensure consistently high product quality.

Auditcheck

1 Request	2 Auditcheck	3 Result

Please convey test sample 1x

✓ Ferrous: 3.00 mm
✓ Stainless steel 304: 5.00 mm
Non-ferrous: 4.00 mm

Menu-guided Audit-Check

Logbook
(filtered logbook entries)

226	19. Apr 2022, 10:59:15	(2) Product 2 Auditcheck passed
225	19. Apr 2022, 10:59:15	(2) Product 2 Test sample detected: Non-ferrous, 4.00 mm
223	19. Apr 2022, 10:58:53	(2) Product 2 Test sample detected: Stainless steel 304, 5.00 mm
221	19. Apr 2022, 10:58:36	(2) Product 2 Test sample detected: Ferrous, 3.00 mm
220	19. Apr 2022, 10:58:18	(2) Product 2 Auditcheck requested
218	19. Apr 2022, 10:58:06	(2) Product 2 Auditcheck failed

Documentation of the Audit-Check in the logbook

The 3 steps of the Audit-Check

1 Request

The prompt to perform the Audit-Check appears on the display of the control unit. The frequency of these checks can be set manually.
- Hourly
- Daily
- Interval
- Product counter
- Product change

2 Audit-Check

The test bodies must be promoted as shown in the dialog box. Material type, diameter and the maximum permissible signal strength can be selected and adjusted manually.

3 Result

The results of the individual test bodies and the result of the test are transferred to the logbook and stored.

Audit-Check failed

In the event of an incorrect Audit-Check, the device immediately sets the operating status to ‚Error' and stops the conveyor line. Possible causes are:
- Test body not detected
- Timeout
- Signal of the test body outside the defined range
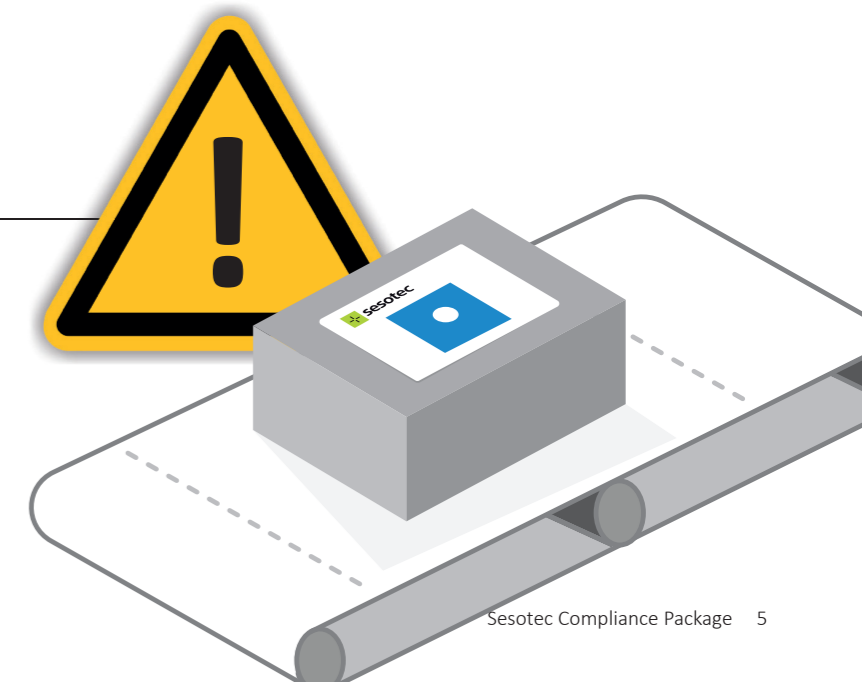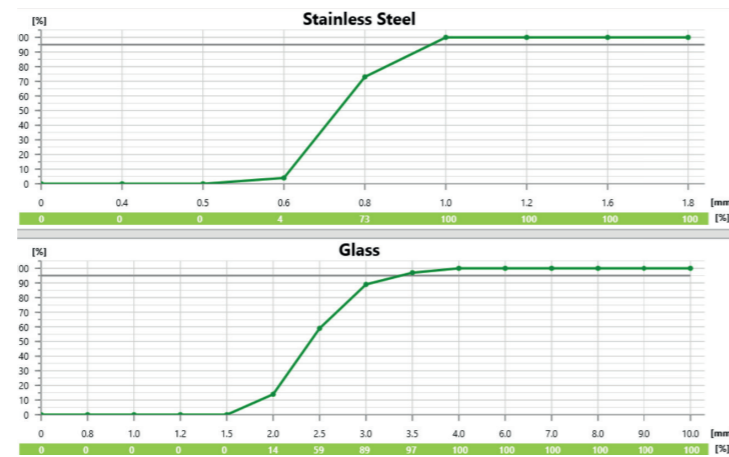
Sensitivity Prediction

The sensitivity prediction is automatically updated after each teach-in process. After changes of sensitivity-dependent parameters, it is calculated and enables an automatic determination of the detection sensitivity of various foreign bodies.

Sensitivities forecast during X-ray inspection

The **„Sensitivity Prediction"** enables automatic determination of the detection sensitivity of stainless steel and glass during an X-ray inspection. The test cards with 100 test bodies made of glass and stainless steel are available in all sizes and stored in the software. This information is calculated along with the product's gray value image as if a product with a test body were being recorded.

All information on detection sensitivity is calculated from these generated images and displayed in a graph.

Graphical representation of the calculated detection sensitivities for stainless steel and glass for an X-ray system

Prediction of metal detection sensitivities

After the teach-in process, the software automatically gives the most suitable Inspection Level (IL) with associated sensitivities for ferrous, stainless steel, and non-ferrous metals. The IL with the predicted sensitivities that most reliably meet customer requirements can then be selected.

	FE	SS	NFE
IL-53	1,5	3,0	2,0
IL-44	1,2	2,5	2,0
IL-33	1,2	2,0	1,5
IL-23	1,5	2,5	1,5
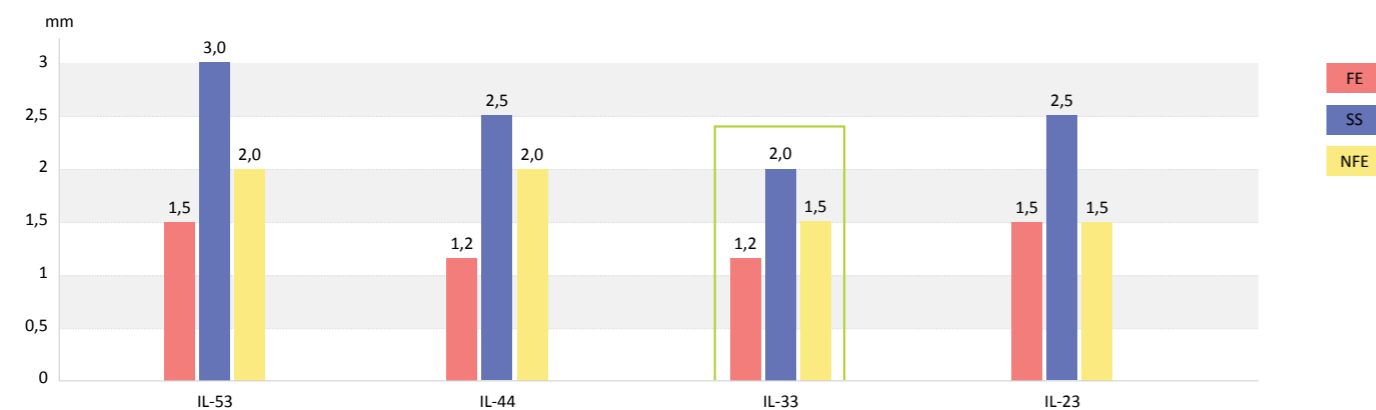
Advantages for the customer

- Instant overview of the sensitivity level
- Simple adjustment with the required detection sensitivity
- Enormous time savings during the teach-in process
- Easy determination of the best inspection level for the product to be inspected

Compliance Mode

In Compliance Mode, the sensitivity can be set to factory or audit standards at the push of a button to produce compliantly and, at the same time, to reduce the false rejection rate. Process stability is thus constantly maintained.

Reduction of false reject rate (F.R.R.) & minimization of good material loss:

In compliance mode, **the X-ray unit** adjusts the software filters accordingly during the teach-in process in order to reliably detect the specified test specimens.

The metal detector, in turn, adjusts the trigger level of the set product to reliably detect the specified test specimens.

PATENTED by Sesotec

Active compliance mode

The user can store in the system what is to be done in the event of non-compliance with the configured sensitivity prediction whether a warning message or even a stop of the production line.

Advantages for the customer

- Compliance with the food safety standards
- Savings in labor, packaging and product waste
- Increase in production efficiency
- Display of the predicted power and conformity values with simple verification
- For X-ray inspection systems: less relearning for difficult product

Integrated Compliance Monitoring (ICM)

Integrated Compliance Monitoring controls the detection capability of the inspection system. This continuous, internal control of detection requirements leads to immediate detection of deviations and increases the stability of the production process.

The two-step approach to Integrated Compliance Monitoring

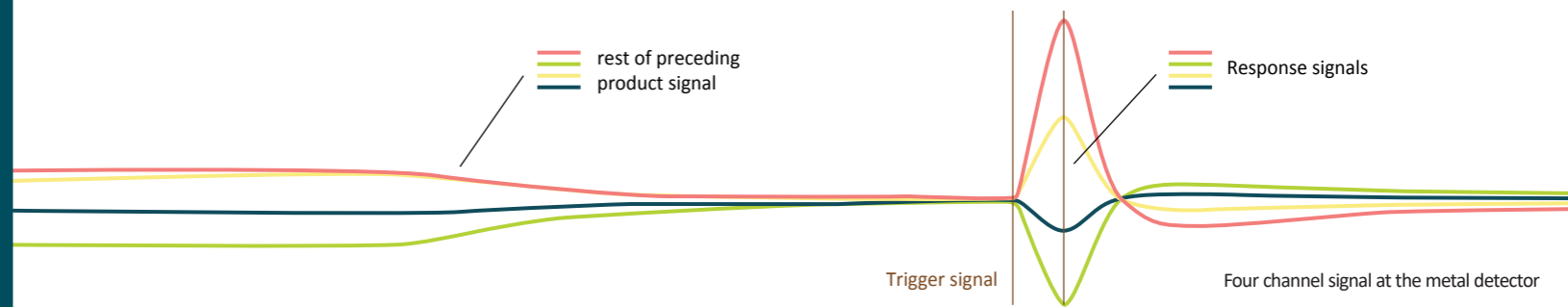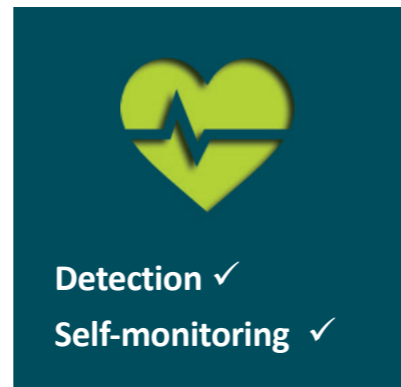**1** **Self-monitoring of the detection unit of metal detectors**

Integrated Compliance Monitoring oversees the detector by inserting a four-channel signal into the signal chain which is specially adapted to the product to be tested during the training process. This signal is transmitted in short intervals and thus determines the condition of the machine.

1 **Self-monitoring of the detection unit of X-ray inspection systems**

Integrated Compliance Monitoring surveils the recorded gray-scale images of the products. For this, test bodies stored in the software are compared with the product images and offset against the limit values matched.

2 **Compliance Mode**

The ICM generates an alarm condition to report non-compliance when the detection prediction exceeds the value of the conformity mode. In this case, the production line is stopped automatically. All results and incidents are noted in the logbook and time stamped.

Advantages for the customer

- Compliance with food safety standards
- Savings in working time, packaging and product waste
- Increase in production efficiency
- Increase in product quality
- Reduces the risk of inadequate quality controls and records

Detection ✓
Self-monitoring ✓

rest of preceding product signal

Response signals

Trigger signal

Four channel signal at the metal detector

Functionality in metal detection

- The detector is controlled by an internal test signal, which is tuned to the product during the learning process.
- For easy and quick verification, the predicted power as well as the conformity values are displayed.
- As soon as the received information does not match the specific requirements, the system issues an error or warning message, depending on the configuration.

Functionality during X-ray inspection

- The initial sensitivities are calculated directly after the autotrain process and saved.
- The current sensitivity for stainless steel and glass are continuously and automatically checked after a fixed time interval.
- The sensitivity limits can be set manually.
- If the limit values are exceeded, there will be an error or warning message.

Integrated Validation Process (IVP)

The Integrated Validation Process (IVP) is a documentation tool and yields proof that the desired quality objectives for the respective product have been achieved. The goal or result of the Integrated Validation process is a Sesotec-created certificate with the validation results.

Next Service
Sesotec Service Hotline:
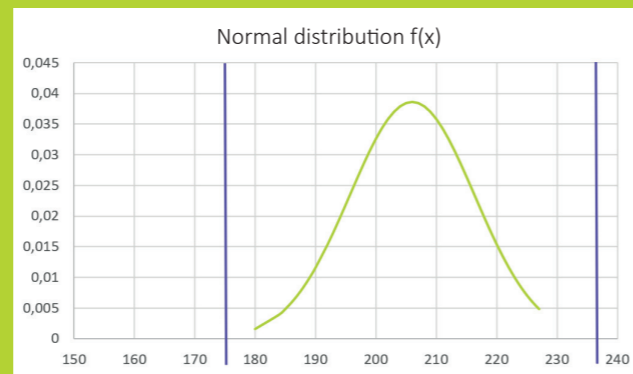+49 (0)8554 308 173

Validation in 2 steps

1. Calculation of the false reject rate (F.R.R.)
Takes place without a test body and is only determined on the basis of the product signal calculated. In this case, the product must be used without a test body to be conveyed at least 10 times.

2. Calculation of the probability of detection (P.O.D.)
This is done by conveying the product at least 10 times per test body.

Service offer

For all other existing installations (of the type G+, Primus+, GO, Intuity) our service offers the Manufacturer's Validation as a service. The service includes the preparation of the annual validation certificate and of a maintenance report. Among other things, a repeat test of the probability of detection (P.O.D.) is carried out at the most unfavorable point of the metal detector using the specified test bodies.

Customer benefits:
- Performance of the retest including evaluation and documentation
- Determination of the limit value to provide further security for the customer during daily routine testing

Advantages for the customer

- Consistent validation
- Automatic creation of a backup of all settings in order to be able to restore the device to the state of validation
- Records in the metal detector
- Setting realistic testing standards and ensuring compliance
- Reliable reporting data
- The user automatically receives a notification for the next validation, eliminating the need to apply stickers that wash off
- The certificate can be saved in PDF format on a USB stick

Normal distribution f(x)

The granted validation certificate of Sesotec's service is unique because it provides proof of the normal distribution of the tested product and another limit or control point for daily routine tests.

Certificate symbol

The certificate icon is green when the created certificate is active and becomes orange if validation is needed again soon.

Validation certificate

All product data and detection signal information are evaluated in the detector and merged. A validation certificate is then created as a PDF file.

Active validation

The validation process yields the proof that the desired quality objectives for the product are being achieved.

- Based on multiple samples, a confidence score is applied to the data to ensure that the results are consistent.
- The metal detector keeps track and automatically warns if, when revalidation is required before the next audit.

+ sesotec

Certificate of Validation

Report Number:	1234567890-1-23	**Date of Validation:**	11.04.2022, 09:06
Job Number:	Sesotec-3590	**Date of Next Validation Due:**	01.07.2022
Company:	Meat Ball Ltd.	**Validating Technician:**	Harry Berry
Address:	Hamway 3	**Contact:**	Mike Butcher
	Seattle,	**Email Address:**	butcher@meatball.com
	12854	**Telephone:**	5678 - 36801

Metal Detector Configuration

Model:	INTUITY	**Aperture Size:**	350/150
Serial:	1234567890	**Reject Type:**	Standalone / None
Device Name:	INTUITY	**Threshold:**	50 (Standard)
Line Name:	Line 1	**Inspection Level:**	IL-33

Product Details

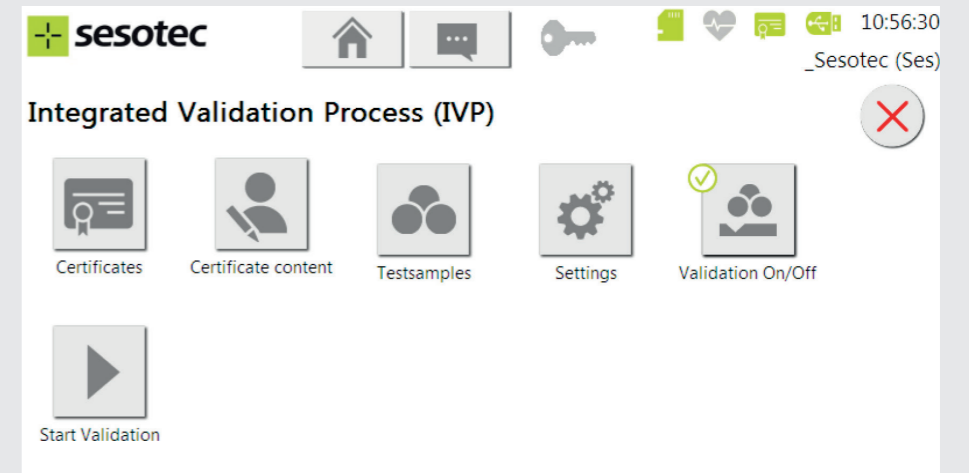|	
Name:	Product 1
Length:	20,5cm
Width:	12cm
Height:	5cm
Temperature:	10C
Belt Speed:	700 mm/s
Pack Rate:	60ppm

Validation Results

Test Sample Information	Test Sample Identification	Average Signal	Signal Niveau	Probability of Detection	Confirmed Rejections	Result
FE, 1.75 mm	IN-4560	251 %	186.9 %	---	10/10	Passed
NFE, 2.00 mm	IN-2485	292 %	218.3 %	---	10/10	Passed
SS 304, 2.50 mm	IN-9718	262 %	216.9 %	---	10/10	Passed

Estimated False Reject Rate: 1.742918% (17.43/1'000), calculated within a conveyance duration of 01:00 min

For any questions or to schedule your next validation please contact Sesotec at +49 8553 308 0 or at info@sesotec.com

Note: The test is performed with the metal sample at the leading edge, middle, and trailing edge of the product (if applicable). The validation was performed with certified test sticks which comply to NIST standards. Metal Detection results can be impacted by the product signals, the results listed above are based on the specific product that was used during this Validation process.

+ sesotec   _Sesotec (Ses)   10:56:30

Integrated Validation Process (IVP)

Certificates   Certificate content   Testsamples   Settings   Validation On/Off

Start Validation

Menu-driven process through validation

![sesotec logo]

You would like to learn more about our technical solutions for food production?

Then contact us directly. We will be happy to advise you.
You can reach us via:

+49 (0) 8554 308-0   www.sesotec.com