The Accredited Calibration Certificate for Laboratory Balances Overview, Definitions, Information

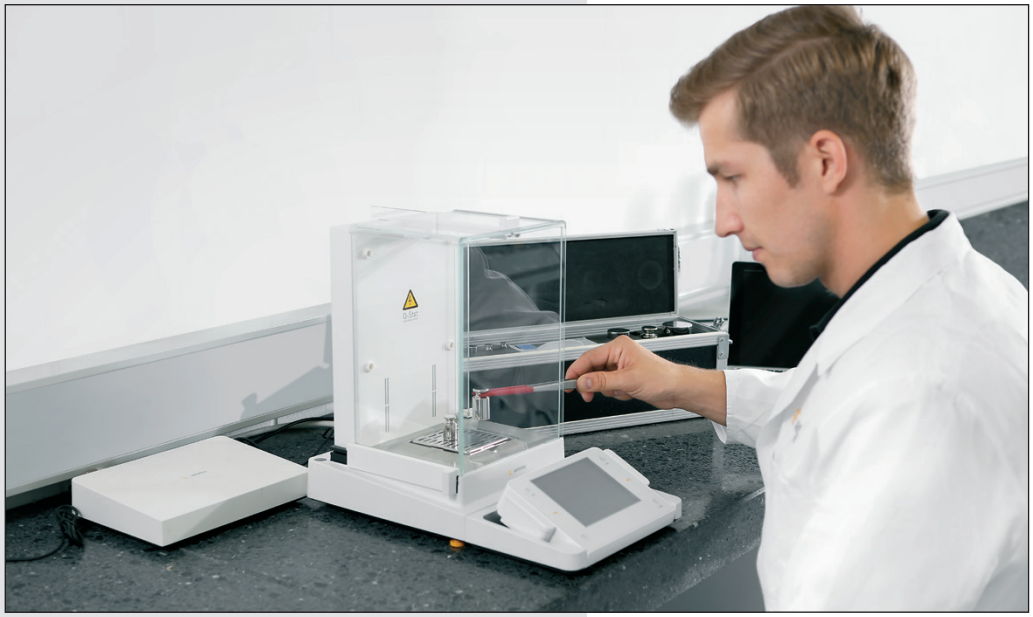
turning science into solutions

Accurate and Reliable Results

The requirements on accuracy and reliability of laboratory data are continuously growing. Leading regulatory requirements and quality management standards, such as the ISO 9000 series and GMP, call for regular calibration of inspection, measuring and test equipment. Only in this way can accurate, reliable and traceable measurement results be ensured over the long term.

Sartorius Service is accredited for compliance with ISO 17025 in many countries and is authorized to issue calibration certificates for laboratory balances. Therefore, complete traceability of your measuring equipment to your national standards and confidence in your measurement and test results are ensured.

The intention of this brochure is to explain the individual parts of the Sartorius calibration certificate and key terms. In addition, it provides information on how to interpret calibration results and the uncertainty of measurement.



Calibration Certificate Issued by Sartorius

The Sartorius calibration certificate is divided into two parts:

1. First, we consider the official, predefined template that shows all information on the object or instrument calibrated, the measured results and the respective uncertainties of measurement.
2. Second, we provide a more detailed Appendix along with an interpretation of the measured results.

Official Part of the Calibration Certificate | Basic Information

The first page of the calibration certificate contains information and specifications that are important for control of inspection, measuring and test equipment and of its accuracy. Once you have received a calibration certificate, you should always check whether the documents are complete and the information entered is correct.

Description of information entered:

1 Accreditation and ILAC-MRA[1] Symbol
- Sartorius has been accredited in various countries by the respective national accreditation bodies (e.g., DAkkS, UKAS, ANAB, etc.) and is authorized to perform on-site calibration of weighing instruments.
- The ILAC-MRA recognizes the calibration certificates issued by ILAC-MRA in all ILAC member nations.

2 Calibration Marks
- Upper part: certificate number
- Middle part: registration number of the calibration laboratory
- Lower part: year and month of calibration

3 Basic Calibration Data
- Basic data of the weighing instrument and the customer are stated in this area.
- **If the calibration certificate is to be used as proof of traceability, this data must match that given for test equipment management.**

4 Stamp and Signatures
- The stamp of the calibration laboratory, the date of issue of the calibration certificate (may differ from the actual calibration date), the signatures of the laboratory manager and the person who performed calibration are provided at the bottom of the first page.

sartorius Calibration Laboratory Accredited According to DIN EN ISO/IEC 17025 for Electronic Balances/Scales

accredited by the / akkreditiert durch die
Deutsche Akkreditierungsstelle GmbH

1

als Kalibrierlaboratorium im / as calibration laboratory in the
Deutschen Kalibrierdienst DKD

DAkkS Deutsche Akkreditierungsstelle D-K-19398-02-00

2

Calibration Certificate *Kalibrierschein*	**Calibration mark** *Kalibrierzeichen*
	19398-02-00
	2017-11

3

Object *Gegenstand*	**Electronical scale** ***Elektronische Waage***
Manufacturer *Hersteller*	**Sartorius**
Type *Typ*	**SECURA224-1S**
Serial / QM Ident No. *Serien-/Prüfmittel-Nr.*	**333333333**
Customer *Auftraggeber*	**Sartorius Lab Instruments GmbH & Co. KG**
	Otto-Brenner-Str. 20 37079 Göttingen
Order No. *Auftragsnummer*	**12345678**
Number of pages of the certificate *Anzahl der Seiten des Kalibrierscheins*	**5**
Date of calibration *Datum der Kalibrierung*	**20.11.2017**

This calibration certificate documents the traceability to national standards, which realize the units of measurement according to the International System of Units (SI). The DAkkS is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates.The user is obliged to have the object recalibrated at appropriate intervals.

Dieser Kalibrierschein dokumentiert die Rückführung auf nationale Normale zur Darstellung der Einheiten in Übereinstimmung mit dem Internationalen Einheitensystem (SI). Die DAkkS ist Unterzeichner der multilateralen Übereinkommen der European co-operation for Accreditation (EA) und der International Laboratory Accreditation Cooperation (ILAC) zur gegenseitigen Anerkennung der Kalibrierscheine. Für die Einhaltung einer angemessenen Frist zur Wiederholung der Kalibrierung ist der Benutzer verantwortlich.

This calibration certificate may not be reproduced other than in full except with the permission of both the Deutsche Akkreditierungsstelle GmbH and the issuing laboratory. Calibration certificates without signature are not valid.

Dieser Kalibrierschein darf nur vollständig und unverändert weiterverbreitet werden. Auszüge oder Änderungen bedürfen der Genehmigung sowohl der Deutschen Akkreditierungsstelle GmbH als auch des ausstellenden Kalibrierlaboratoriums. Kalibrierscheine ohne Unterschrift haben keine Gültigkeit.

4

DAkkS Calibration Laboratory D-K-19398-02-00 SARTORIUS

20.11.2017

Head of the calibration laboratory *Leiter des Kalibrierlaboratoriums*: Dipl. Ing. Norbert Schnell

Person in charge *Bearbeiter*: Max Mustermann

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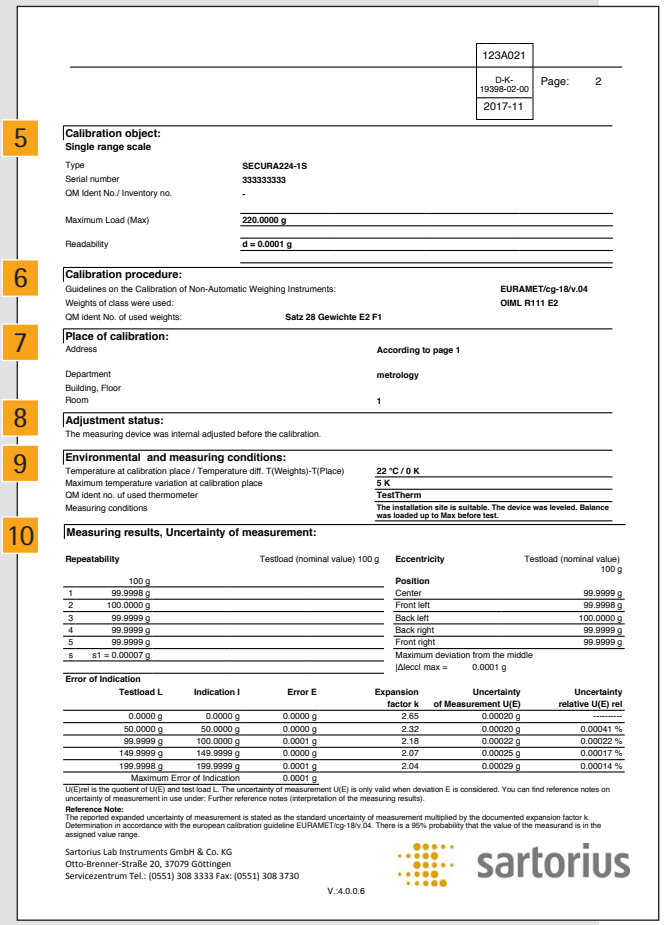
Page / Seite 1

V.:4.0.0.6

Page 1

Important Information:
- The user shall be responsible for having calibration repeated within a reasonable deadline.
- Calibration certificates may be disseminated only in their complete and unamended form. Excerpts or changes require prior approval both from the respective accreditation body and from the calibration laboratory that issued the particular certificate.

[1] ILAC: International Laboratory Accreditation Cooperation; MRA: Mutual Recognition Arrangement



123A021

D-K-19398-02-00 Page: 2

2017-11

5 **Calibration object:**
Single range scale

Type	SECURA224-1S
Serial number	333333333
QM Ident No./ Inventory no.	-
Maximum Load (Max)	220.0000 g
Readability	d = 0.0001 g

6 **Calibration procedure:**

Guidelines on the Calibration of Non-Automatic Weighing Instruments:	EURAMET/cg-18/v.04
Weights of class were used:	OIML R111 E2
QM ident No. of used weights:	Satz 28 Gewichte E2 F1

7 **Place of calibration:**

Address	According to page 1
Department	metrology
Building, Floor	
Room	1

8 **Adjustment status:**
The measuring device was internal adjusted before the calibration.

9 **Environmental and measuring conditions:**

Temperature at calibration place / Temperature diff. T(Weights)-T(Place)	22 °C / 0 K
Maximum temperature variation at calibration place	5 K
QM ident no. uf used thermometer	TestTherm
Measuring conditions	The installation site is suitable. The device was leveled. Balance was loaded up to Max before test.

10 **Measuring results, Uncertainty of measurement:**

Repeatability Testload (nominal value) 100 g

	100 g
1	99.9998 g
2	100.0000 g
3	99.9999 g
4	99.9999 g
5	99.9999 g
s	s1 = 0.00007 g

Eccentricity Testload (nominal value) 100 g

Position	
Center	99.9999 g
Front left	99.9998 g
Back left	100.0000 g
Back right	99.9999 g
Front right	99.9999 g

Maximum deviation from the middle
|Δeccl max = 0.0001 g

Error of Indication

Testload L	Indication I	Error E	Expansion factor k	Uncertainty of Measurement U(E)	Uncertainty relative U(E) rel
0.0000 g	0.0000 g	0.0000 g	2.65	0.00020 g	---------
50.0000 g	50.0000 g	0.0000 g	2.32	0.00020 g	0.00041 %
99.9999 g	100.0000 g	0.0001 g	2.18	0.00022 g	0.00022 %
149.9999 g	149.9999 g	0.0000 g	2.07	0.00025 g	0.00017 %
199.9998 g	199.9999 g	0.0001 g	2.04	0.00029 g	0.00014 %
Maximum Error of Indication		0.0001 g			

U(E)rel is the quotient of U(E) and test load L. The uncertainty of measurement U(E) is only valid when deviation E is considered. You can find reference notes on uncertainty of measurement in use under: Further reference notes (interpretation of the measuring results).

Reference Note:
The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the documented expansion factor k. Determination in accordance with the european calibration guideline EURAMET/cg-18/v.04. There is a 95% probability that the value of the measurand is in the assigned value range.

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V.:4.0.0.6

Page 2

5 Calibration Object

- This area lists the following: basic metrological data (type, serial number and QM identification and inventory numbers), as well as the calibrated ranges.
- Depending on your calibration requirements, the maximum load for calibration may differ from the maximum capacity of weighing instrument. **Please note that in this case, the calibration certificate will serve only as proof of traceability up to the maximum load used for calibration.**
- For multiple range and multi-interval weighing instruments: the various calibrated (partial) weighing ranges with their particular maximum capacity and readability are listed.

6 Calibration Procedure

- This is performed according to EURAMET Calibration Guide No. 18: Guidelines on the Calibration of Non-Automatic Weighing Instruments of the current version 4.0 (11/2015). This Guide can be downloaded from the EURAMET website at www.euramet.org free of charge.
- Sartorius uses weights of classes E2, F1 and M1 according to the classification of the OIML International Recommendation "R111 Weights of classes E1, E2, F1, F2, M1, M1–2, M2, M2–3 and M3", in the current version of "Edition 2004".

7 Place of Calibration

- Calibration of the particular weighing instrument is valid only for the location specified on the calibration certificate. **If this instrument is moved to a different place, the environmental conditions of this new location, for example, may differ from those at the original place to a such a considerable extent that recalibration of the instrument is required.**

8 Adjustment Status

- Depending on your calibration requirements and type of weighing instrument, calibration can be performed with and | or without prior adjustment.
- Basically, adjustment should be performed before calibration as the former generally reduces the difference between the value indicated and the nominal value of the load actually placed on the pan.
- Calibration without prior adjustment can be advisable for quality control to check or prove the accuracy of the measured values recorded; this is known as an "as found" calibration procedure.
- Calibration after adjustment is called "as left calibration".

9 Environmental and Measuring Conditions

- Information is provided here on temperature and place of calibration; the difference in temperature between the environment and the weights used (to estimate the possible effects of convection); maximum temperature variation at the place of calibration; the thermometer used; and the measuring conditions.
- The measuring conditions do not have a direct influence on the calibration result, but rather are used primarily for information and documentation.

10 Measuring Results and Uncertainty of Measurement

- This is where the measurements of the repeatability and eccentricity error of indication, as well as the calculated errors and uncertainties of measurement, are specified. A list of the results concludes the official part of the calibration certificate.

Further Reference Notes | Interpretation of the Measuring Results

11 Uncertainty of Measurement in Use

- Calibration can and may only provide information about the difference between the nominal value of the weight placed on the pan and the value indicated by the weighing instrument exactly at the particular time this is done and for exactly the weight used in calibration.
- The Sartorius calibration certificate additionally shows an estimate of the uncertainty of measurement in use of your weighing instrument.
- The so-called global expanded uncertainty already includes an interpolation of the previously determined error of indication. This means that a respective reading in use no longer has to be corrected. The global uncertainty is given in the form of a linear equation; i.e., with uncertainty contributions of a constant variable and a variable proportional to the reading:

Uncertainty of the Weighing Result Ugl(W):

$$Ugl(W) = 0.00016\ g + 3.49 * 10^{-6} * R$$

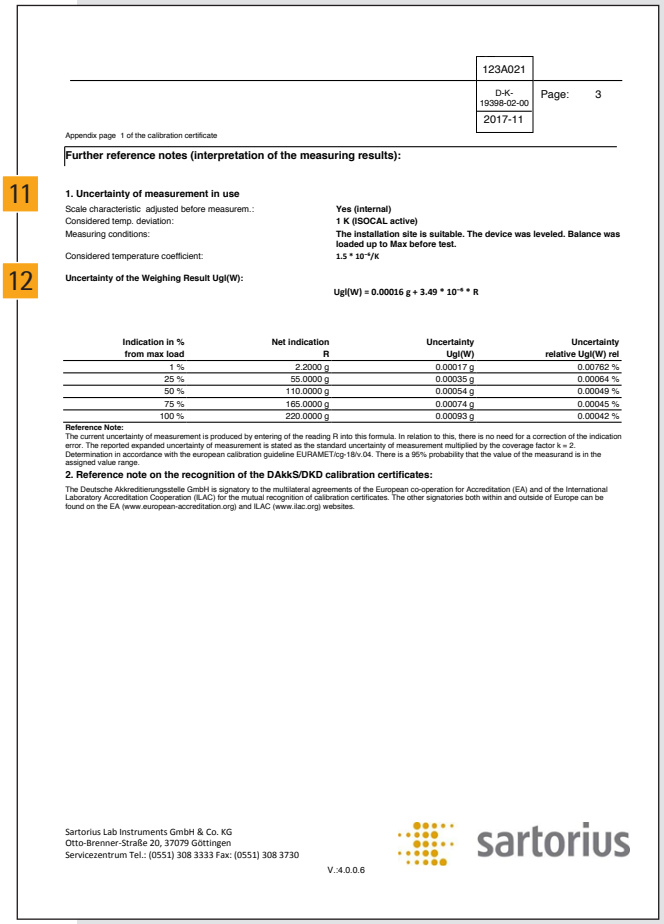
12 Interpretation of the Equation

For a reading of R, the true value will lie within the interval [R-Ugl(W); R+Ugl(W)] with a probability of 95% – hence, for the example above, within the interval [0.999837 g; 1.000163 mg] for a reading of R=1 g.

In most cases, the global expanded uncertainty is a sufficiently good estimate of the uncertainty in use of a weighing instrument and can be directly used in practice. The partial errors for the following aspects are used in the calculation of this uncertainty:

- Rounding at 0
- Rounding when a load is applied
- Repeatability
- Eccentricity error of indication during eccentric loading
- Possible changes in the weighing instrument and | or buoyancy effects caused by changes in temperature at the place of use
- Long-term changes that a weighing instrument undergoes
- Possible effects of taring, creep or hysteresis of the weighing instrument
- Error of indication determined during calibration and the interpolation of this error

In a few special cases (such as when weighing in a protective gas atmosphere), it may be necessary for you to modify the calculation of the uncertainty to accommodate these special conditions.



123A021

D-K-19398-02-00

2017-11

Page: 3

Appendix page 1 of the calibration certificate

Further reference notes (interpretation of the measuring results):

11

1. Uncertainty of measurement in use

Scale characteristic adjusted before measurem.: **Yes (internal)**

Considered temp. deviation: **1 K (ISOCAL active)**

Measuring conditions: **The installation site is suitable. The device was leveled. Balance was loaded up to Max before test.**

Considered temperature coefficient: **1.5 * 10⁻⁶/K**

12

Uncertainty of the Weighing Result Ugl(W):

Ugl(W) = 0.00016 g + 3.49 * 10⁻⁶ * R

Indication in % from max load	Net indication R	Uncertainty Ugl(W)	Uncertainty relative Ugl(W) rel
1 %	2.2000 g	0.00017 g	0.00762 %
25 %	55.0000 g	0.00035 g	0.00064 %
50 %	110.0000 g	0.00054 g	0.00049 %
75 %	165.0000 g	0.00074 g	0.00045 %
100 %	220.0000 g	0.00093 g	0.00042 %

Reference Note:
The current uncertainty of measurement is produced by entering of the reading R into this formula. In relation to this, there is no need for a correction of the indication error. The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k = 2. Determination in accordance with the european calibration guideline EURAMET/cg-18/v.04. There is a 95% probability that the value of the measurand is in the assigned value range.

2. Reference note on the recognition of the DAkkS/DKD calibration certificates:

The Deutsche Akkreditierungsstelle GmbH is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates. The other signatories both within and outside of Europe can be found on the EA (www.european-accreditation.org) and ILAC (www.ilac.org) websites.

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V.:4.0.0.6

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Page 3

Important Information:

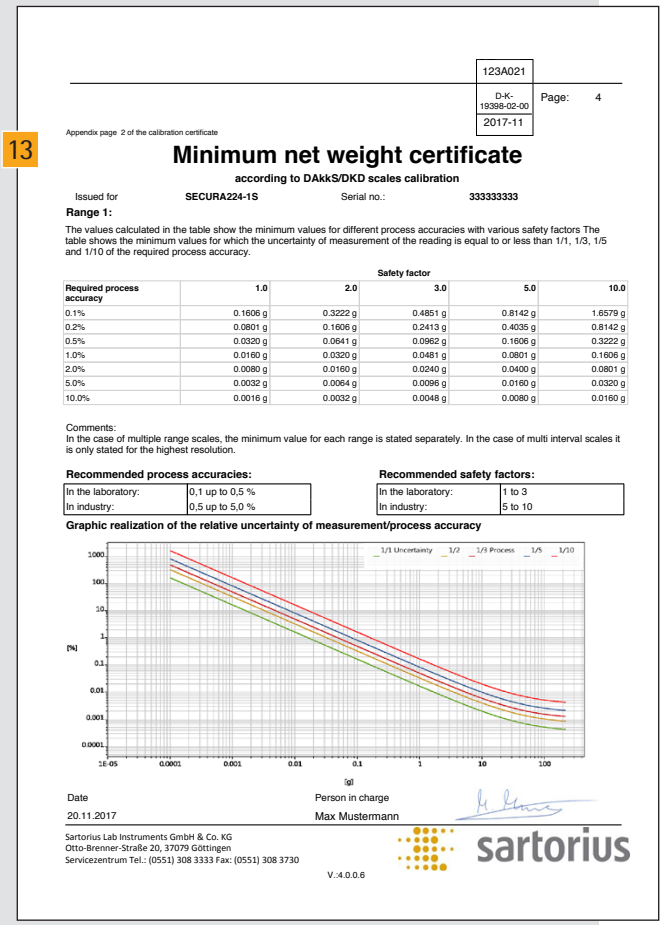
The respective calculations yield information on which actions would reduce the uncertainty of measurement in use. The largest influential factors include adjustment of the weighing instrument; an environment in which the temperature is kept constant at all times as far as possible; and centered loading of the pan during a weighing procedure.

First Appendix:
The Minimum Net Weight Certificate

13 Minimum Net Weight Certificate

- On request, your Sartorius service technician will issue a minimum net weight certificate.
- The minimum net weights for the various process accuracies required and different safety factors are listed on this certificate.

Please note that the minimum net weight of a balance is typically much higher than the smallest possible value displayed by the balance, scale interval d. This is not due to the lack of quality of your balance. Even for a theoretically ideal calibration procedure of an ideal balance – under ideal conditions in use – a global expanded uncertainty of $U_{gl}(W) \approx 0{,}8 \cdot d$ would be yielded for a single range balance with $d=d_0=d_L$ as the result of the finite resolution of this balance. Therefore, the minimum net weight for common process accuracies and safety factors would always be several times the resolution of the balance (see Table 1).



123A021

D-K-19398-02-00 Page: 4

2017-11

Appendix page 2 of the calibration certificate

13

Minimum net weight certificate

according to DAkkS/DKD scales calibration

Issued for **SECURA224-1S** Serial no.: **333333333**

Range 1:

The values calculated in the table show the minimum values for different process accuracies with various safety factors The table shows the minimum values for which the uncertainty of measurement of the reading is equal to or less than 1/1, 1/3, 1/5 and 1/10 of the required process accuracy.

	Safety factor				
Required process accuracy	**1.0**	**2.0**	**3.0**	**5.0**	**10.0**
0.1%	0.1606 g	0.3222 g	0.4851 g	0.8142 g	1.6579 g
0.2%	0.0801 g	0.1606 g	0.2413 g	0.4035 g	0.8142 g
0.5%	0.0320 g	0.0641 g	0.0962 g	0.1606 g	0.3222 g
1.0%	0.0160 g	0.0320 g	0.0481 g	0.0801 g	0.1606 g
2.0%	0.0080 g	0.0160 g	0.0240 g	0.0400 g	0.0801 g
5.0%	0.0032 g	0.0064 g	0.0096 g	0.0160 g	0.0320 g
10.0%	0.0016 g	0.0032 g	0.0048 g	0.0080 g	0.0160 g

Comments:
In the case of multiple range scales, the minimum value for each range is stated separately. In the case of multi interval scales it is only stated for the highest resolution.

Recommended process accuracies:

In the laboratory:	0,1 up to 0,5 %
In industry:	0,5 up to 5,0 %

Recommended safety factors:

In the laboratory:	1 to 3
In industry:	5 to 10

Graphic realization of the relative uncertainty of measurement/process accuracy

Date 20.11.2017

Person in charge Max Mustermann

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V.:4.0.0.6

Page 4

Safety Factor

Required Process Accuracy	1	2	3	5	10
0.1%	800 d	1600 d	2400 d	4000 d	8000 d
0.2%	400 d	800 d	1200 d	2000 d	4000 d
0.5%	160 d	320 d	480 d	800 d	1600 d
1%	80 d	160 d	240 d	400 d	800 d
2%	40 d	80 d	120 d	200 d	400 d
5%	16 d	32 d	48 d	80 d	160 d
10%	8 d	16 d	24 d	40 d	80 d

Table 1: The theoretically **smallest possible** minimum net weights of a laboratory balance with a resolution of d for a few common process accuracies and safety factors (rounded values).

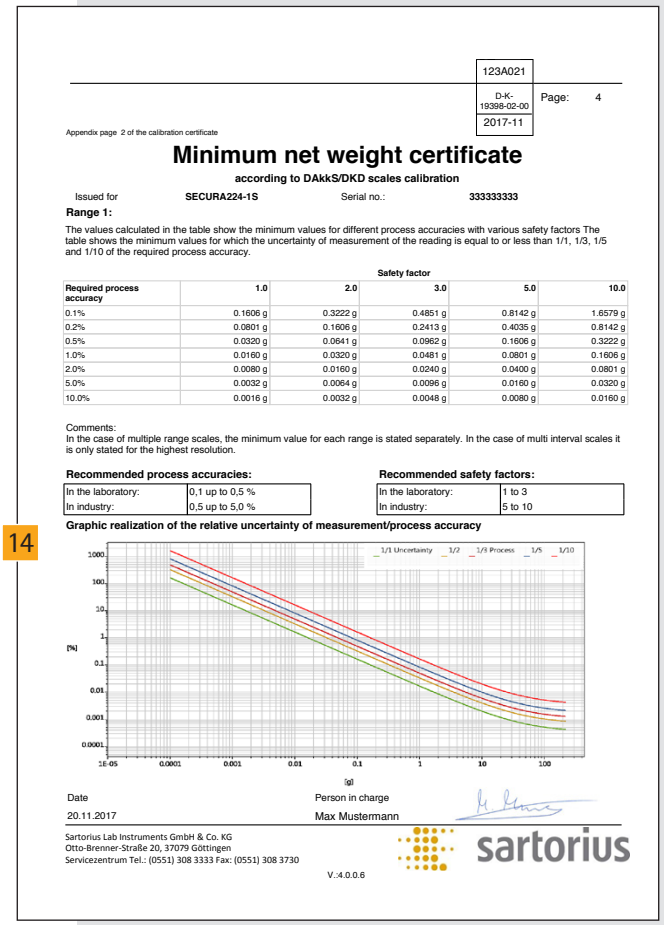
14 Diagram of the Relative Uncertainty of Measurement | Process Accuracy Based on the Example of the Minimum Net Weight

- The following equation of the global uncertainty of measurement in use contains two partial errors:
  1. One variable proportional to the indication
  2. One constant variable

Uncertainty of the Weighing Result Ugl(W):

$$U_{gl}(W) = 0.00016\ g + 3.49 * 10^{-6} * R$$

- The relative uncertainty of measurement $U_{gl,rel}(W)=U_{gl}(W)/W$ is not a constant. Instead, it increases as loads decrease.
- If the uncertainty is not to exceed a specified maximum permissible relative uncertainty $U_{max,rel}$ (e.g., required by a targeted relative process accuracy), this will inevitably lead to a specific minimum net weight of R_{min} below which the relative uncertainty will be higher.
- Often, the required process accuracy is divided by a safety factor in order to obtain the maximum permissible relative uncertainty.
- On the calibration certificate, a corresponding example is calculated for a required process accuracy of p=1% and a safety factor of k_S=3.
- For other values of p and k_S, the respective minimum net weight can also be read off the diagram: The value is located on the x-axis where the corresponding curve intersects the required process accuracy on the y-axis (five curves are plotted with the typical safety factors of 1, 2, 3, 5 and 10). The example of p=1 % and k_S=3 is plotted for illustration.
- For any values of p and k_s, the minimum net weight can be calculated using the formula $R_{min} = \alpha_{gl} / ([p/k_s]-\beta_{gl})$ in which α_{gl} is the constant proportion (in the example α_{gl} = 0.00016 g) and β_{gl} the factor of the proportion proportional to the display (in the example $\beta_{gl}=3.49 \times 10^{-6}$).



123A021

D-K-19398-02-00 2017-11

Page: 4

Appendix page 2 of the calibration certificate

Minimum net weight certificate

according to DAkkS/DKD scales calibration

Issued for **SECURA224-1S** Serial no.: **333333333**

Range 1:

The values calculated in the table show the minimum values for different process accuracies with various safety factors The table shows the minimum values for which the uncertainty of measurement of the reading is equal to or less than 1/1, 1/3, 1/5 and 1/10 of the required process accuracy.

Required process accuracy	Safety factor 1.0	2.0	3.0	5.0	10.0
0.1%	0.1606 g	0.3222 g	0.4851 g	0.8142 g	1.6579 g
0.2%	0.0801 g	0.1606 g	0.2413 g	0.4035 g	0.8142 g
0.5%	0.0320 g	0.0641 g	0.0962 g	0.1606 g	0.3222 g
1.0%	0.0160 g	0.0320 g	0.0481 g	0.0801 g	0.1606 g
2.0%	0.0080 g	0.0160 g	0.0240 g	0.0400 g	0.0801 g
5.0%	0.0032 g	0.0064 g	0.0096 g	0.0160 g	0.0320 g
10.0%	0.0016 g	0.0032 g	0.0048 g	0.0080 g	0.0160 g

Comments:
In the case of multiple range scales, the minimum value for each range is stated separately. In the case of multi interval scales it is only stated for the highest resolution.

Recommended process accuracies:

In the laboratory:	0,1 up to 0,5 %
In industry:	0,5 up to 5,0 %

Recommended safety factors:

In the laboratory:	1 to 3
In industry:	5 to 10

Graphic realization of the relative uncertainty of measurement/process accuracy

14

Date: 20.11.2017

Person in charge: Max Mustermann

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Page 4

Important Information:

- When reading values off the diagram, please note that the graph is a double logarithmic plot. A value that is located in the center, for example, between 1 g and 2 g, is not 1.5 g, as on a linear plot, but rather 1.3 g. This type of plot was chosen in this case in order to better represent small loads.
- The minimum net weight calculated in this example is for p=0.1% and k_S=1, **not** the same as the smallest net weight according to USP Chapter 41 (see Section 4). These values are terms that are similarly designated, but are defined and calculated differently. If you need to weigh according to USP, the minimum net weight shown on this calibration certificate cannot be used in this case. You will need a separate USP certificate issued by Sartorius.
- If you use legal-for-trade or verified balances; i.e. balances that are used in applications subject to legal control, the minimum capacity will continue to apply as the limit below which no weighing operations may be carried out for applications subject to legal metrology.

Second Appendix: Conformity Certificate

15 Conformity Certificate

On request, your Sartorius service technician will issue a conformity certificate. Unlike weights, for which the OIML R111-1 International Recommendation defines the maximum permissible errors for the nominal value of the various classes, there are no normative requirements for weighing instruments. Therefore, conformity statements can only refer to the specifications given by the user.

Before calibration, you as the user need to provide the specifications to be met.
Such requirements can be the following, for example:

- The specifications given by the manufacturer of the weighing instrument. Please note that these are often values that refer to optimal conditions. If a balance is operated under less than ideal conditions, the calibration results can be significantly higher, without these being based on a defect of this instrument. This is why many manufacturers separately provide "typical" specifications.
- Results of previous calibrations are given to ensure that a weighing instrument has not significantly deteriorated in performance. To prevent statistical variations of a value from being incorrectly interpreted as deterioration in the performance of a balance, a certain supplement should be added to the worst calibration result obtained so far.
- Statements on process requirements and their mandatory accuracy are given, such as a certain process accuracy with a safety factor that must be met for a specific minimum net weight. Alternatively, a maximum permissible uncertainty of a weighing result can be stated for a specific net weight.

On the conformity certificate, only the calibration results are compared with the specifications you, the user, have provided. If it turns out that specific requirements or specifications are not met, your Sartorius service technician will be happy to advise you on the appropriate action to take, for example:

- Improve the environmental conditions
- Change the location of your balance
- Have your balance repaired or
- Use a different balance model

15

123A021

D-K-19398-02-00

2017-11

Page: 5

Appendix page 3 of the calibration certificate

Conformity certificate

according to DAkkS/DKD scales calibration

Issued for **SECURA224-1S** Serial no.: **333333333**

First Measurement:

The conformity certificate certifies the compliance with the requirements made for the abovementioned scale. The basis for this are the measured values determined during the DAkkS/DKD scales calibration. The conformity statements relate to the uncertainties of measurement in use.

Conformity statements for compliance with customer specifications:

These conformity statements refer to the calibration results on the official part of the calibration certificate (see pp. 2 ff.)

1. Standard deviation of the repeatability measurement (s):

Calibration result	Customer specifications	Condition fulfilled
0.0001 g	0.0001 g	Yes

2. Max. difference in the measurement of the eccentricity error (|Δ lecc I max):

Calibration result	Customer specifications	Condition fulfilled
0.0001 g	0.0010 g	Yes

3. Maximum error (E) of indication during performance test:

Calibration result	Customer specifications	Condition fulfilled
0.0001 g	0.0002 g	Yes

Conformity statements on the customer's process requirements:

Relate to the uncertainties of measurement in use (see Appendix 1 of the calibration certificate).

A) At a process accuracy of 0.10 % with the safety factor 1 the scale maintains a minimum net weight of 0.5000 g.

B) With a net weight of 100.0000 g the scale does not exceed the max. uncertainty Ugl(W) of 0.0100 g. This corresponds to a maximum deviation of 100 digits.

Date 20.11.2017

Person in charge Max Mustermann

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V.:4.0.0.6

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Page 5

Sartorius offers the following statement options on a conformity certificate.
The gray shaded fields stand for values that you can define:

16 **1. Standard Deviation of the Repeatability Measurement (s):**

Calibration result	Customer specification	Condition fulfilled
0.0001 g	0.0001 g	Ja

17 **2. Maximum Difference in the Measurement of the Eccentricity Error (|Δlecc|max):**

Calibration result	Customer specification	Condition fulfilled
0.0001 g	0.0010 g	Ja

18 **3. Maximum Error (E) of Indication During the Performance Test:**

Calibration result	Customer specification	Condition fulfilled
0.0001 g	0.0002 g	Ja

Examples of Conformity Statements on Process Requirements:

A) At a process accuracy of 0.10 % with a safety factor of 2, the minimum net weight of 0.5000 g is maintained by the balance.

B) With a net weight of 100.00 g the balance does not exceed the maximum uncertainty U_{gl}(W) of 0.01 g in use.
This corresponds to a maximum deviation of 100 digits.

123A021

D-K-19398-02-00 2017-11

Page: 5

Appendix page 3 of the calibration certificate

Conformity certificate

according to DAkkS/DKD scales calibration

Issued for **SECURA224-1S** Serial no.: **333333333**

First Measurement:

The conformity certificate certifies the compliance with the requirements made for the abovementioned scale. The basis for this are the measured values determined during the DAkkS/DKD scales calibration. The conformity statements relate to the uncertainties of measurement in use.

Conformity statements for compliance with customer specifications:

These conformity statements refer to the calibration results on the official part of the calibration certificate (see pp. 2 ff.)

16 1. Standard deviation of the repeatability measurement (s):

Calibration result	Customer specifications	Condition fulfilled
0.0001 g	0.0001 g	Yes

17 2. Max. difference in the measurement of the eccentricity error (|Δ lecc l max):

Calibration result	Customer specifications	Condition fulfilled
0.0001 g	0.0010 g	Yes

18 3. Maximum error (E) of indication during performance test:

Calibration result	Customer specifications	Condition fulfilled
0.0001 g	0.0002 g	Yes

Conformity statements on the customer's process requirements:

Relate to the uncertainties of measurement in use (see Appendix 1 of the calibration certificate).

A) At a process accuracy of 0.10 % with the safety factor 1 the scale maintains a minimum net weight of 0.5000 g.

B) With a net weight of 100.0000 g the scale does not exceed the max. uncertainty Ugl(W) of 0.0100 g. This corresponds to a maximum deviation of 100 digits.

Date 20.11.2017

Person in charge Max Mustermann

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Otto-Brenner-Straße 20, 37079 Göttingen
Servicezentrum Tel.: (0551) 308 3333 Fax: (0551) 308 3730

V.:4.0.0.6

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Page 5

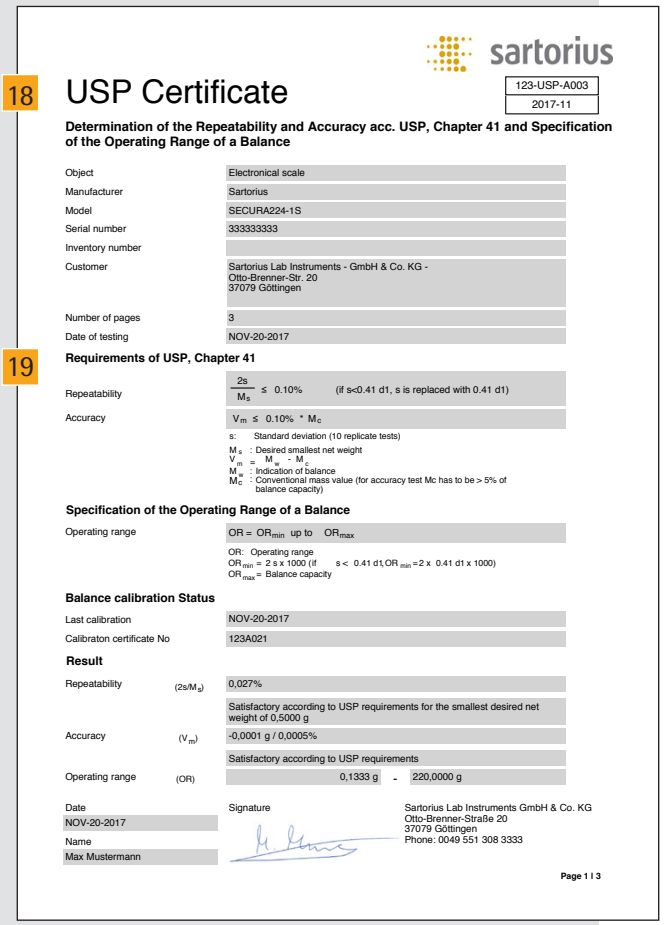
USP Certificate

18 USP Certificate

On request, your Sartorius service technician will additionally or alternatively issue a USP[2] certificate for your balance. For this purpose, your service technician will need information in advance to perform further measurements (e.g., at least 10 measurements for determining the repeatability).

19 United States Pharmacopeia Chapter 41

- Chapter 41 of the United States Pharmacopeia specifies the requirements on the repeatability and the accuracy of a balance, which will be tested by your Sartorius service technician as a prerequisite for issuing a USP2 certificate.
- In addition, this chapter describes a requirement on the operating range of a balance, which is shown on the certificate.



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18 USP Certificate

123-USP-A003
2017-11

Determination of the Repeatability and Accuracy acc. USP, Chapter 41 and Specification of the Operating Range of a Balance

Object	Electronical scale
Manufacturer	Sartorius
Model	SECURA224-1S
Serial number	333333333
Inventory number	
Customer	Sartorius Lab Instruments - GmbH & Co. KG - Otto-Brenner-Str. 20 37079 Göttingen
Number of pages	3
Date of testing	NOV-20-2017

19 **Requirements of USP, Chapter 41**

Repeatability	$\frac{2s}{M_s} \leq 0.10\%$ (if s<0.41 d1, s is replaced with 0.41 d1)
Accuracy	$V_m \leq 0.10\% * M_c$

s: Standard deviation (10 replicate tests)
M_s : Desired smallest net weight
$V_m = M_w - M_c$
M_w : Indication of balance
M_c : Conventional mass value (for accuracy test Mc has to be > 5% of balance capacity)

Specification of the Operating Range of a Balance

Operating range	OR = OR_{min} up to OR_{max}

OR: Operating range
OR_{min} = 2 s x 1000 (if s < 0.41 d1, OR_{min} = 2 x 0.41 d1 x 1000)
OR_{max} = Balance capacity

Balance calibration Status

Last calibration	NOV-20-2017
Calibraton certificate No	123A021

Result

Repeatability	($2s/M_s$)	0,027%
		Satisfactory according to USP requirements for the smallest desired net weight of 0,5000 g
Accuracy	(V_m)	-0,0001 g / 0,0005%
		Satisfactory according to USP requirements
Operating range	(OR)	0,1333 g - 220,0000 g

Date: NOV-20-2017
Name: Max Mustermann
Signature

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Page 1 I 3

Page 1

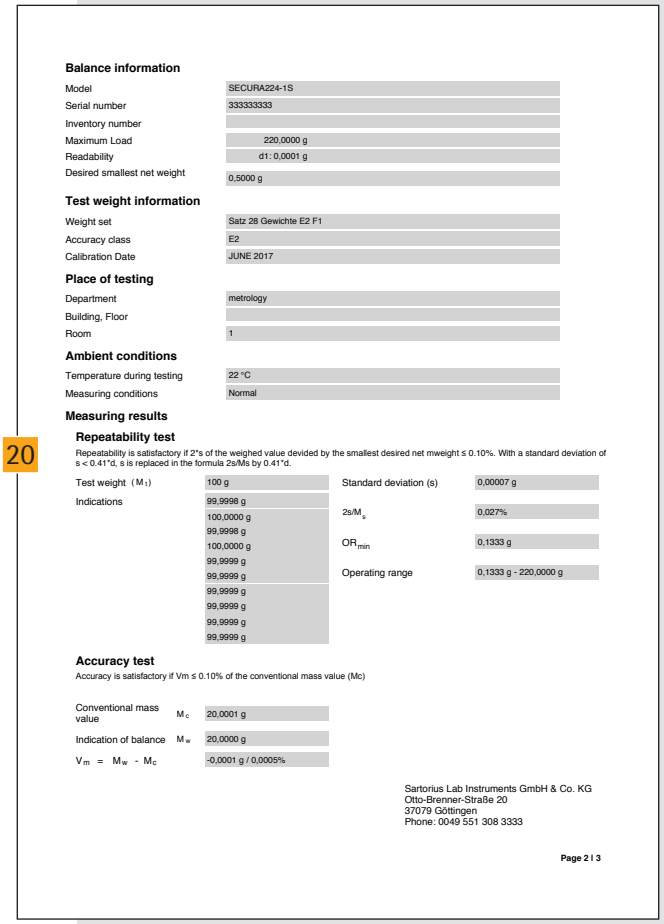
Important Information:

Strictly speaking, a USP certificate is not an integral part of accredited calibration. Because the USP requires a calibrated balance, however, we recommend on principle that you have USP testing performed together with accredited calibration.

[2] USP = United States Pharmacopeia

20 Repeatability Test

- To assess the repeatability of a balance, repeatability is satisfactory if two times the standard deviation of the weighed value is less than or equal to 0.1% of the smallest net weight M_S to be used on the balance:
  $2 \cdot s \leq 0{,}1\ \% \cdot M_S$
- To ensure that a balance with excellent repeatability does not yield a minimum net weight of 0 g, s is replaced by $0.41 \cdot d$, if $s < 0.41 \cdot d$. This enables the minimum limit $OR_{min}=M_S$ of the operating range OR to be directly calculated, on the one hand. The variable s also makes it possible to determine whether the desired smallest net weight the user plans to use on the balance according to the inequality stated above is fulfilled, on the other. The operating range OR of a balance is ultimately yielded by the smallest net weight $OR_{min}=M_S$ and the maximum capacity of the balance $OR_{max}=Max.$



Balance information

Model	SECURA224-1S
Serial number	333333333
Inventory number	
Maximum Load	220,0000 g
Readability	d1: 0,0001 g
Desired smallest net weight	0,5000 g

Test weight information

Weight set	Satz 28 Gewichte E2 F1
Accuracy class	E2
Calibration Date	JUNE 2017

Place of testing

Department	metrology
Building, Floor	
Room	1

Ambient conditions

Temperature during testing	22 °C
Measuring conditions	Normal

Measuring results

20

Repeatability test

Repeatability is satisfactory if 2*s of the weighed value devided by the smallest desired net mweight ≤ 0.10%. With a standard deviation of s < 0.41*d, s is replaced in the formula 2s/Ms by 0.41*d.

Test weight (M_1)	100 g	Standard deviation (s)	0,00007 g
Indications	99,9998 g	$2s/M_s$	0,027%
	100,0000 g	OR_{min}	0,1333 g
	99,9998 g	Operating range	0,1333 g - 220,0000 g
	100,0000 g		
	99,9999 g		
	99,9999 g		
	99,9999 g		
	99,9999 g		
	99,9999 g		
	99,9999 g		

Accuracy test

Accuracy is satisfactory if Vm ≤ 0.10% of the conventional mass value (Mc)

Conventional mass value	M_c	20,0001 g
Indication of balance	M_w	20,0000 g
$V_m = M_w - M_c$		-0,0001 g / 0,0005%

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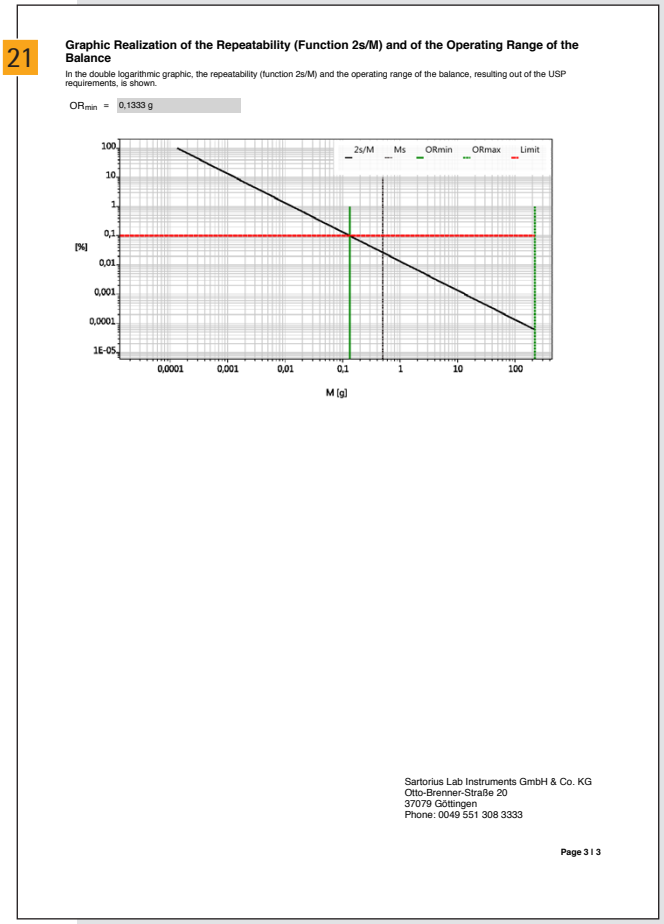
Page 2 I 3

Page 2

21 Graphic Realization of the Function 2s/M and of the Operating Range of the Balance

- The minimum net weight is also shown in a double logarithic graph for illustration. The operating range OR of the balance is depicted by the vertical green lines. The desired smallest net weight is shown by the vertical black line.
- If this line is within the operating range, the minimum net weight can be achieved under USP conditions. However, if this line is on the left, and thus below the operating range of the balance, the desired smallest net weight cannot be achieved under USP conditions.



21

Graphic Realization of the Repeatability (Function 2s/M) and of the Operating Range of the Balance

In the double logarithmic graphic, the repeatability (function 2s/M) and the operating range of the balance, resulting out of the USP requirements, is shown.

OR_{min} = 0,1333 g

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Page 3 I 3

Page 3

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Further information on calibration is available on our service website at www.sartorius.com/service

www.sartorius.com

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