



Product Service

**Mehr Wert.  
Mehr Vertrauen.**

TÜV SÜD Product Service GmbH · Ridlerstraße 65 · 80339 München · Deutschland

seca gmbh & co. kg  
Hammer Steindamm 3-25  
22089 Hamburg

|                       |              |                                                  |                   |               |          |
|-----------------------|--------------|--------------------------------------------------|-------------------|---------------|----------|
| Your Ref/Name         | Our Ref/Name | Tel. /E-Mail                                     | Fax               | Date          | Page     |
| CN MDR Extension V002 | PSE 2126332  | +49 40 840521-137<br>Martin.szepannek@tuvsud.com | +49 40 840521-198 | 16. June 2023 | 1 von 10 |

## Notified Body Confirmation Letter

**Reference: Change Notification MDR Extension V002 – PSE 2126332**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.**

This letter confirms that, TÜV SÜD Product Service GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0123 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer.

**seca gmbh & co. kg  
Hammer Steindamm 3-25  
22089 Hamburg**

**SRN: DE-MF-000005469**

Sitz: München  
Handelsregister München HRB 85742  
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unter [www.tuvsud.com/impressum](http://www.tuvsud.com/impressum)

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Geschäftsführung:  
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**TUV®**

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Ridlerstraße 65  
80339 München  
Deutschland



Product Service

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below, see attachment:

- Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation in accordance with Article 59(1) of the MDR or
- provided evidence that a competent authority of a Member State had granted an exemption from the applicable conformity assessment procedure in accordance with Article 97(1) of the MDR respectively,

by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

TÜV SÜD Product Service GmbH  
Medical and Health Services

**Signatur:** *M. Szepannek*

**E-Mail:** Martin.Szepannek@tuvsud.com

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Martin Szepannek  
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH  
Medical and Health Services

**Signatur:** *Hoyer Julia*  
Hoyer Julia (16. Juni 2023 12:59 GMT+2)

**E-Mail:** Julia.Hoyer@tuvsud.com

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Julia Hoyer  
Head of Certification Body - Deputy



## ATTACHMENT

**Table 1: Devices covered by this letter and for which the TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive**

| Device name / Reference<br>(Basic UDI-DI under MDR application)                                                                                                                                                                       | MDR Device classification<br>(as proposed by the manufacturer and verified at the pre-/ application stage)                  | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device                                               | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| seca 201 / 2011717009<br>seca 201 / 2011817009<br>seca 203 / 2031717009<br><br>(401203000000000000050QL)                                                                                                                              | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 206 / 2061717009<br>seca 206 / 2061817139<br><br>(401203000000000000055QW)                                                                                                                                                       | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 207 / 2071714008<br>seca 207 / 2071814008<br>seca 210 / 2101721004<br>seca 210 / 2101821004<br>seca 416 / 4161721009<br>seca 416 / 4161821009<br>seca 417 / 4171721009<br>seca 417 / 4171821009<br><br>(401203000000000000031QG) | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 212 / 2121717009<br>seca 212 / 2121817009<br><br>(401203000000000000051QN)                                                                                                                                                       | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 213 / 2131721009<br>seca 213 / 2131821009<br>seca 213 / 2131721759<br>seca 216 / 2161814009<br>seca 217 / 2171721009<br>seca 217 / 2171821009<br>seca 222 / 2221714008<br>seca 222 / 2221814008<br><br>(401203000000000000030QE) | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 220 / 2201714003<br>seca 220 / 2201814003<br>seca 223 / 2231717998<br>seca 223 / 2231814998<br>seca 224 / 2241714004<br><br>(401203000000000000036QS)                                                                            | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 232 n / 2321717008<br>seca 232 / 2321817008<br>seca 233 / 2331714004<br>seca 233 / 2331814004<br><br>(401203000000000000043QP)                                                                                                   | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;            |



| Device name / Reference<br>(Basic UDI-DI under MDR application)                                                                                                                                                                                                                                                                                                      | MDR Device classification<br>(as proposed by the manufacturer and verified at the pre-/ application stage)                  | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device                                               | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification                                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                             | <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD                                                          | NB 0123                                                                                                                                        |
| seca 234 / 2341717009<br>seca 234 / 2341817009<br><br>(401203000000000000056QY)                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 264 / 2641900099<br>seca 264 / 2641900009<br>seca 274 / 2741900099<br>seca 274 / 2741900009<br><br>(401203000000000000041QK)                                                                                                                                                                                                                                    | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 284 / 2841000109<br>seca 284 / 2841300109<br>seca 284 / 2841310109<br>seca 285 / 2857000009<br>seca 285 / 2857000199<br>seca 285 / 2857000289<br>seca 285 / 2857000649<br>seca 285 / 2857000669<br><br>(401203000000000000057R2)                                                                                                                                | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 286 / 2861000009<br>seca 286 / 2861300009<br>seca 286 / 2861300209<br>seca 286 / 2861300909<br>seca 286 r / 2866900209<br>seca 287 / 2877000009<br>seca 287 / 2877000099<br>seca 287 / 2877000229<br>seca 287 / 2877000289<br>seca 287 / 2877000649<br>seca 287 / 2877000799<br>seca 287 / 2877000889<br>seca 287 / 2877000899<br><br>(401203000000000000058R4) | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 310 / 3101017654<br><br>(401203000000000000035QQ)                                                                                                                                                                                                                                                                                                               | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 334 / 3341021008<br>seca 334 / 3341321008<br>seca 334 / 3341321619<br><br>(401203000000000000047QX)                                                                                                                                                                                                                                                             | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 333 i / 3331021004<br>seca 333 i / 3331021009<br>seca 333 i / 3337321009<br>seca 336 / 3367021008<br>seca 336 / 3367021098<br>seca 336 / 3367021223                                                                                                                                                                                                             | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or                                                                                            | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;            |



| Device name / Reference<br>(Basic UDI-DI under MDR application)                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | MDR Device classification<br>(as proposed by the manufacturer and verified at the pre-/ application stage)                  | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device                                               | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| seca 336 / 3367021283<br>seca 336 / 3367021438<br>seca 336 / 3367021644<br>seca 336 / 3367021668<br>seca 336 / 3367021688<br>seca 336 i / 3367321009<br>seca 336 i / 3367321099<br>seca 336 i / 3367321229<br>seca 336 i / 3367321289<br>seca 336 i / 3367321439<br>seca 336 i / 3367321649<br>seca 336 i / 3367321669<br>seca 336 i / 3367321689<br><br>(401203000000000000042QM)                                                                                                                                                          |                                                                                                                             | <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD                                                          | NB 0123                                                                                                                                        |
| seca 374 / 3741021004<br>seca 374 / 3741321004<br>seca 376 / 3767021008<br>seca 376 / 3767021098<br>seca 376 / 3767021228<br>seca 376 / 3767021288<br>seca 376 / 3767021438<br>seca 376 / 3767021649<br>seca 376 / 3767021668<br>seca 376 / 3767021688<br>seca 376 / 3767021259<br>seca 376 / 3767021128<br><br>(401203000000000000046QV)                                                                                                                                                                                                   | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 384 / 3847017009<br>seca 384 / 3847017099<br>seca 384 / 3847017229<br>seca 384 / 3847017649<br>seca 384 / 3847017669<br>seca 384 / 3847017689<br>seca 384 / 3847017259<br>seca 384 / 3847017129<br>seca 385 / 3857017094<br>seca 385 / 3857017124<br>seca 834 / 8347017094<br><br>(401203000000000000037QU)                                                                                                                                                                                                                            | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 634 / 6341321008<br>seca 634 / 6341921024<br>seca 635 / 6357021004<br>seca 635 / 6357021094<br>seca 635 / 6357021224<br>seca 635 / 6357021284<br>seca 635 / 6357021649<br>seca 635 r / 6357021999<br>seca 644 / 6441021108<br>seca 644 / 6441321108<br>seca 645 / 6457021003<br>seca 645 / 6457021193<br>seca 645 / 6457021223<br>seca 645 / 6457021283<br>seca 645 / 6457021649<br>seca 656 / 6561321103<br>seca 657 / 6577021003<br>seca 657 / 6577021193<br>seca 657 / 6577021223<br>seca 657 / 6577021283<br>seca 657 / 6577021644 | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |



| Device name / Reference<br>(Basic UDI-DI under MDR application)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | MDR Device classification<br>(as proposed by the manufacturer and verified at the pre-/ application stage)                  | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device                                               | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification                                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| seca 657 r / 6577921193<br>seca 664 / 6641321103<br>seca 665 / 6657021003<br>seca 665 / 6657021193<br>seca 665 / 6657021223<br>seca 665 / 6657021283<br>seca 665 / 6657021433<br>seca 665 / 6657021644<br>seca 667 / 6677021619<br>seca 667 / 6677021629<br>seca 667 / 6677021759<br>seca 674 / 6741321103<br>seca 675 / 6757021003<br>seca 675 / 6757021193<br>seca 675 / 6757021223<br>seca 675 / 6757021283<br>seca 675 / 6757021433<br>seca 675 / 6757021644<br>seca 676 / 6761021108<br>seca 676 / 6761321108<br>seca 676 r / 6761321994<br>seca 677 / 6777021008<br>seca 677 / 6777021198<br>seca 677 / 6777021228<br>seca 677 / 6777021288<br>seca 677 / 6777021438<br>seca 677 / 6777021644<br>seca 677 r / 6777021994<br>seca 684 / 6841321107<br>seca 684 r / 6841321994<br>seca 685 / 6857021003<br>seca 685 / 6857021193<br>seca 685 / 6857021223<br>seca 685 / 6857021283<br>seca 685 / 6857021644<br>seca 685 r / 6857021994<br><br>(4012030000000000000039QY) |                                                                                                                             |                                                                                                                                              |                                                                                                                                          |
| seca 700 s / 7001321993<br>seca 700 s / 7001121993<br>seca 700 s / 7001021993<br>seca 700 s / 7001021933<br>seca 711 s / 7117021998<br><br>(4012030000000000000060QP)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows: G3M 18 03 12163 068; NB 0123 |
| seca 700 / 7001321008<br>seca 700 / 7001121008<br>seca 700 / 7001021658<br>seca 700 / 7001021008<br>seca 711 / 7117021004<br><br>(4012030000000000000028QT)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows: G3M 18 03 12163 068; NB 0123 |
| seca 703 s / 7031021997<br>seca 703 s / 7031321997<br>seca 703 s / 7037821004<br>seca 704 s / 7047721093<br>seca 704 s / 7047721123<br><br>(4012030000000000000061QR)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows: G3M 18 03 12163 068; NB 0123 |
| seca 703 / 7031321007<br>seca 704 / 7047021008<br>seca 704 / 7047021098<br>seca 704 / 7047021228                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <input type="checkbox"/> N/A<br><br>or                                                                                      | <input checked="" type="checkbox"/> N/A<br><br>or                                                                                            | <input type="checkbox"/> N/A<br><br>or                                                                                                   |



| Device name / Reference<br>(Basic UDI-DI under MDR application)                                                                                                                                                                                                                                                                                                                                                                                                | MDR Device classification<br>(as proposed by the manufacturer and verified at the pre-/ application stage)          | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device                                       | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| seca 704 / 7047021288<br>seca 704 / 7047021438<br>seca 704 / 7047021649<br>seca 704 / 7047021668<br>seca 704 / 7047021688<br>seca 704 r / 7047021999<br>seca 704 r / 7047921129<br>seca 704 / 7047021259<br>seca 704 / 7047021128<br><br><b>(401203000000000000038QW)</b>                                                                                                                                                                                      | <input checked="" type="checkbox"/> Class I devices with a measuring function                                       | <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD                                                  | <input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123                                       |
| seca 725 / 7251021004<br>seca 725 / 7251021654<br>seca 725 / 7251021944<br>seca 745 / 7457021004<br><br><b>(401203000000000000027QR)</b>                                                                                                                                                                                                                                                                                                                       | <input type="checkbox"/> N/A<br>or<br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br>or<br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br>or<br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 755 / 7551021004<br>seca 755 / 7551321004<br>seca 755 / 7551421004<br>seca 756 / 7567021004<br>seca 786 / 7862021004<br><br><b>(401203000000000000053QS)</b>                                                                                                                                                                                                                                                                                              | <input type="checkbox"/> N/A<br>or<br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br>or<br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br>or<br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 755 s / 7551021998<br>seca 755 s / 7551321998<br>seca 756 s / 7567021998<br>seca 786 s / 7862021998<br><br><b>(401203000000000000063QV)</b>                                                                                                                                                                                                                                                                                                               | <input type="checkbox"/> N/A<br>or<br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br>or<br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br>or<br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 727 / 7271321868<br>seca 757 / 7577021008<br>seca 757 / 7577021124<br>seca 757 / 7577021228<br>seca 757 / 7577021288<br>seca 757 / 7577021434<br>seca 757 / 7577021644<br>seca 757 / 7577021664<br>seca 757 / 7577021698<br><br><b>(401203000000000000048QZ)</b>                                                                                                                                                                                          | <input type="checkbox"/> N/A<br>or<br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br>or<br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br>or<br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 750 / 7501017008<br>seca 750 / 7501019008<br>seca 750 / 7501119008<br>seca 750 / 7501319003<br>seca 760 / 7601019004<br>seca 760 / 7601025004<br>seca 760 / 7601026008<br>seca 760 / 7601028008<br>seca 760 / 7601029008<br>seca 760 / 7601419004<br>seca 760 / 7601425004<br>seca 760 / 7601426004<br>seca 760 / 7601428004<br>seca 760 / 7601429004<br>seca 761 / 7617019008<br>seca 761 / 7617019128<br>seca 762 / 7621019008<br>seca 762 / 7621319004 | <input type="checkbox"/> N/A<br>or<br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br>or<br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br>or<br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |



| Device name / Reference<br>(Basic UDI-DI under MDR application)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | MDR Device classification<br>(as proposed by the manufacturer and verified at the pre-/ application stage)                  | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device                                               | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>(401203000000000000054QU)</b><br>seca 769 / 7691321004<br>seca 799 / 7997021009<br>seca 799 / 7997021099<br>seca 799 / 7997021229<br>seca 799 / 7997021289<br>seca 799 / 7997021439<br>seca 799 / 7997021649<br>seca 799 / 7997021669<br>seca 799 / 7997021689<br>seca 799 / 7997021259<br>seca 799 / 7997021129                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| <b>(401203000000000000052QQ)</b><br>seca 769 s / 7691321998<br>seca 799 s / 7997021304<br><br><b>(401203000000000000062QT)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 777 / 7771721004<br>seca 777 / 7771821004<br>seca 787 / 7871721004<br>seca 787 / 7871821004<br>seca 797 / 7971721004<br>seca 797 / 7971821004<br><b>(401203000000000000059R6)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 869 / 8691021004<br>seca 869 / 8691321004<br>seca 874 / 8741021653<br>seca 874 / 8741021714<br>seca 874 / 8741321009<br>seca 874 dr / 8741341109<br>seca 874 dr / 8741341259<br>seca 874 dr / 8741341389<br>seca 874 dr / 8741341399<br>seca 874 dr / 8742721654<br>seca 875 / 8757021124<br>seca 875 / 8757021289<br>seca 875 / 8757021094<br>seca 876 / 8761321004<br>seca 877 / 8777021004<br>seca 877 / 8777021094<br>seca 877 / 8777021224<br>seca 877 / 8777021434<br>seca 877 / 8777021649<br>seca 877 / 8777021664<br>seca 877 / 8777021684<br>seca 877 / 8777021259<br>seca 877 / 8777021124<br>seca 878 / 8787021009<br>seca 878 / 8787021099<br>seca 878 / 8787021229<br>seca 878 / 8787021649<br>seca 878 / 8787021129<br>seca 878 dr / 8787041009<br>seca 878 dr / 8787041019<br>seca 878 dr / 8787041099<br>seca 878 dr / 8787041119<br>seca 878 dr / 8787041219<br>seca 878 dr / 8787041229 | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |



| Device name / Reference<br>(Basic UDI-DI under MDR application)                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | MDR Device classification<br>(as proposed by the manufacturer and verified at the pre-/ application stage)                  | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device                                               | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification                                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| seca 878 dr / 8787041259<br>seca 878 dr / 8787041289<br>seca 878 dr / 8787041319<br>seca 878 dr / 8787041389<br>seca 878 dr / 8787041419<br>seca 878 dr / 8787041429<br>seca 878 dr / 8787041439<br>seca 878 dr / 8787041649<br>seca 878 dr / 8787041669<br>seca 878 dr / 8787041689<br>seca 878 dr / 8787041699<br>seca 878 dr / 8787041129<br>seca 899 / 8997021004<br>seca 899 / 8997021094<br>seca 899 / 8997021224<br>seca 899 / 8997021284<br>seca 899 / 8997021649<br>seca 899 / 8787041129<br>(4012030000000000000029QV) |                                                                                                                             |                                                                                                                                              |                                                                                                                                                |
| seca 954 / 9541309007<br>seca 954 r / 9541309997<br>seca 955 / 9557021124<br>seca 955 / 9557021124<br>seca 957 / 9577021094<br>seca 957 / 9577021004<br>seca 957 / 9577021759<br>seca 959 / 9597021002<br>seca 959 / 9597021092<br>seca 959 / 9597021226<br>seca 959 / 9597021286<br>seca 959 / 9597021439<br>seca 959 / 9597021649<br>seca 959 / 9597021669<br>seca 959 / 9597021689<br>seca 959 / 9597021929<br>seca 959 r / 9597921929<br>(4012030000000000000049R3)                                                          | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |
| seca 952 / 9521309009<br>seca 956 / 9567021009<br>seca 956 / 9567021099<br>seca 956 / 9567021229<br>seca 956 / 9567021289<br>seca 956 / 9567021439<br>seca 956 / 9567021649<br>seca 956 / 9567021669<br>seca 956 / 9567021689<br>seca 956 / 9567021259<br>seca 956 / 9567021129<br>(4012030000000000000040QH)                                                                                                                                                                                                                    | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Class I devices with a measuring function | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD | <input type="checkbox"/> N/A<br><br>or<br><br><input checked="" type="checkbox"/> Certification as follows:<br>G3M 18 03 12163 068;<br>NB 0123 |



**Table 2: Devices covered by this letter and for which the TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device                                                | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| N/A; all devices in scope are subject to Table 1.   | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Class III<br><input type="checkbox"/> Class IIb implantable non-WET device<br><input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET<br><input type="checkbox"/> Class IIa<br><input type="checkbox"/> Class I devices placed on the market in sterile condition<br><input type="checkbox"/> Class I devices with a measuring function<br><input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments<br><input type="checkbox"/> Class III implantable custom-made device | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD: | <input checked="" type="checkbox"/> N/A<br><br>or<br><br><input type="checkbox"/> Certification as follows:<br>Certificate #:<br>Certificate #:<br><br>or<br><br><input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives<br><br>or<br><br><input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |

### Confirmation Letter Version History

| Date       | NB internal reference traceable to each version of the letter | Action                                                                         |
|------------|---------------------------------------------------------------|--------------------------------------------------------------------------------|
| 2023-05-16 | 2126332                                                       | Initial letter                                                                 |
| 2023-06-16 | 2126332                                                       | Typo corrections, Clustering according to BUDI-DI; update acc. latest template |



Product Service

# EC Certificate

## Product Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex VI  
(Devices in Class I with measuring function)

No. G3M 18 03 12163 068

### Manufacturer:

**seca gmbh & co. kg**

Hammer Steindamm 3-25  
22089 Hamburg  
GERMANY



### Facility(ies):

seca gmbh & co. kg  
Hammer Steindamm 3-25, 22089 Hamburg, GERMANY

### Product

### Category(ies):

**Medical scales, measuring devices for  
determination of body length and circumference  
as well as blood pressure meter**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for final inspection and test of the respective devices / device categories in accordance with MDD Annex VI. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

### Report no.:

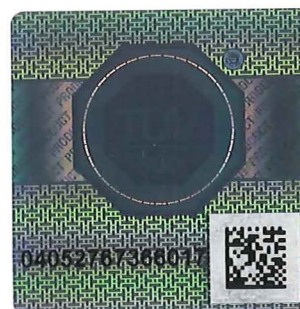
713128921

### Valid from:

2018-05-10

### Valid until:

2023-05-09



Date, 2018-05-03

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 1



## Zertifikat

*Certificate*

### über die Anerkennung eines Qualitätssicherungssystems

*on the approval of a quality system*

Ausgestellt für:

*Issued to:*

seca gmbh & co. kg  
Hammer Steindamm 3-25  
22089 Hamburg

gemäß:

*In accordance with:*

Mess- und Eichverordnung vom 11. Dezember 2014 (MessEV)  
*Measures and Verification Ordinance dated 11 December 2014 (MessEV)*  
in Verbindung mit  
*in connection with*

- Richtlinie **2014/31/EU** vom 26. Februar 2014 (NAWID)  
- *Directive 2014/31/EU of 26 February 2014 (NAWID)*

Messgröße lt. MessEV § 1:  
*Measurand acc. to Measures and  
Verification Ordinance, section 1:*

Masse  
*Mass*

Nr. des Zertifikats:

*Certificate No.:*

DE-M-AQ-PTB123, Revision 4

Gültig bis:

*Valid until:*

26.08.2027

Anzahl der Seiten:

*Number of pages:*

3

Geschäftszeichen:

*Reference No.:*

PTB-9.22-4118711

Nr. der Stelle:

*Body No.:*

0102

Im Auftrag

*On behalf of PTB*

  
Anna Pfaff

Braunschweig, 27.08.2024

Siegel

*Seal*



## Zertifikatsgeschichte

### History of the Certificate

| Zertifikats-Ausgabe<br><i>Issue of the Certificate</i> | Datum<br><i>Date</i> | Änderungen<br><i>Modifications</i>                                                                                                                                                                                                                                                        |
|--------------------------------------------------------|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| DE-M-AQ-PTB123                                         | 20.04.2016           | Erstbescheinigung<br><i>Initial certificate</i><br>(bislang Zertifikat mit der Registrier-Nr. 01.02-05 der Hessischen Eichdirektion),<br>Umstellung von 2009/23/EG auf 2014/31/EU<br>(up to now, certificate no. 01.02-05, Hessische Eichdirektion), change from 2009/23/EC to 2014/31/EU |
| DE-M-AQ-PTB123, Revision 1                             | 27.08.2018           | 1. Reanerkennung,<br>Verlängerung der Gültigkeit um 3 Jahre<br><i>1<sup>st</sup> reapproval, prolongation for another 3 years</i>                                                                                                                                                         |
| DE-M-AQ-PTB123, Revision 2                             | 18.11.2020           | Revision, Ergänzung Standort Pinghu/ China<br><i>Revision, completion site Pinghu/ China</i>                                                                                                                                                                                              |
| DE-M-AQ-PTB123, Revision 3                             | 27.08.2021           | 2. Reanerkennung,<br>Streichung Standort Hangzhou/ China,<br>Verlängerung der Gültigkeit um 3 Jahre<br><i>2<sup>nd</sup> reapproval, prolongation for another 3 years</i>                                                                                                                 |
| DE-M-AQ-PTB123, Revision 4                             | 27.08.2024           | 3. Reanerkennung,<br>Verlängerung der Gültigkeit um 3 Jahre<br><i>3<sup>rd</sup> reapproval, prolongation for another 3 years</i>                                                                                                                                                         |

Diese Revision 4 ersetzt die Revision 3 des Zertifikats Nr. DE-M-AQ-PTB123 vom 27.08.2021, Geschäftszeichen PTB-9.22-4104562.

*This Revision 4 replaces Revision 3 to Certificate No. DE-M-AQ-PTB123 dated 27.08.2021, Reference No. PTB-9.22-4104562*

## Vorbemerkungen

### Preliminary remarks

Die Konformitätsbewertungsstelle der Physikalisch-Technischen Bundesanstalt (PTB) bescheinigt mit diesem Zertifikat, dass das Qualitätssicherungssystem in dem in diesem Zertifikat genannten Geltungsbereich den folgenden Anforderungen entspricht:

*By means of this certificate, the Conformity Assessment Body of the Physikalisch-Technische Bundesanstalt (PTB) certifies that the Quality System complies - within the scope of validity specified in this Certificate - with the following requirements:*

- Anhang II Modul D der Richtlinie 2014/31/EU des Europäischen Parlaments und des Rates vom 26. Februar 2014 zur Angleichung der Rechtsvorschriften der Mitgliedstaaten betreffend die Bereitstellung nichtselbsttätiger Waagen auf dem Markt (ABI L 96 S. 107) in der derzeit geltenden Fassung, Abs. 2.3.2.  
*Annex II Module D of Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96 p. 107) in the currently valid version, para. 2.3.2.*

- Anhang II Modul D1 der Richtlinie 2014/31/EU des Europäischen Parlaments und des Rates vom 26. Februar 2014 zur Angleichung der Rechtsvorschriften der Mitgliedstaaten betreffend die Bereitstellung nichtselbsttätiger Waagen auf dem Markt (ABI L 96 S. 107) in der derzeit geltenden Fassung, Abs. 3.5.2.

*Annex II Module D1 of Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96 p. 107) in the currently valid version, para. 3.5.2.*

Der Zertifikatsinhaber ist berechtigt, die Kennzeichnung für die im Geltungsbereich dieses anerkannten Qualitätssicherungssystems gefertigten Messgeräte mit der PTB-Kennnummer 0102 zu versehen. Die Bewertung basiert auf einer Begutachtung der eingereichten Dokumente und einem Audit im Unternehmen. Das Qualitätssicherungssystem unterliegt der laufenden Überwachung der Konformitätsbewertungsstelle.

*The owner of this certificate is entitled to provide the marking of the measuring instruments which have been produced within the scope of validity of this approved Quality System with the PTB identification number 0102. The assessment is based on an evaluation of the submitted documents and on an audit on site. The quality system is subject to permanent surveillance by the Conformity Assessment Body.*

## Standorte und Gerätearten

### Sites and kinds of instruments

#### Standort 1:

##### Site 1:

**seca gmbh & co.kg**  
Hammer Steindamm 3-25  
22089 Hamburg, Deutschland

#### Messgerätearten:

##### Kinds of measuring instruments:

**EU-Waagen - nichtselbsttätig, elektromechanische Waagen**  
*EU-weighing instruments – non-automatic electromechanical weighing instruments*

#### Standort 2:

##### Site 2:

**seca Medical Measuring Systems (pinghu) co. ltd.**  
Xin Xing Er Rd. No. 1299,  
Pinghu Economic Development Zone  
Pinghu, Zhejiang, China

#### Messgerätearten:

##### Kinds of measuring instruments:

**EU-Waagen - nichtselbsttätig, elektromechanische Waagen**  
*EU weighing instruments, non-automatic, electromechanical instruments*

**EU-Waagen - nichtselbsttätig, mechanische Waagen**  
*EU weighing instruments, non-automatic mechanical instruments*

Die Konformitätsbewertungsstelle führt eine Liste der von diesem Zertifikat abgedeckten Messgerätetypen. Die Liste wird laufend aktualisiert und dem Inhaber des Zertifikats zugeschickt.

*The Conformity Assessment Body maintains a list of the measuring instrument types covered by this Certificate. This list will be kept up to date and sent to the owner of the Certificate.*



## EU-Baumusterprüfbescheinigung

*EU Type-examination Certificate*

Ausgestellt für:  
*Issued to:*

seca gmbh & co. kg  
Hammer Steindamm 3-25  
22089 Hamburg  
Deutschland

Gemäß:  
*In accordance with:*

Anhang II Modul B der Richtlinie 2014/31/EU des Europäischen Parlaments und des Rates vom 26. Februar 2014 zur Angleichung der Rechtsvorschriften der Mitgliedstaaten betreffend die Bereitstellung nichtselbsttätiger Waagen auf dem Markt.  
*Annex II Module B of the Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments.*

Geräteart:  
*Type of instrument:*

Nichtselbsttätige elektromechanische Waage  
*Non-automatic electromechanical weighing instrument*

Typbezeichnung:  
*Type designation:*

BIS01A, BIS01B, BIS01C, BIS01D, BIS01E

Nr. der Bescheinigung:  
*Certificate No.:*

DE-24-NAWID-PTB013

Gültig bis:  
*Valid until:*

15.04.2035

Anzahl der Seiten:  
*Number of pages:*

12

Vorgangsnummer:  
*Reference No.:*

KBS 2-4.3-06.02.03/0366#0001

Notifizierte Stelle:  
*Notified Body:*

0102

Zertifizierung:  
*Certification:*

Braunschweig, 16.04.2025

Bewertung:  
*Evaluation:*

Im Auftrag  
*On behalf of PTB*

Siegel  
*Seal*

Im Auftrag  
*On behalf of PTB*

Dr.-Ing. Oliver Mack

Timo Schwabe



Dieses Zertifikat wurde automatisiert erstellt und ist ohne Unterschrift wirksam. Dieses Zertifikat darf nur unverändert weiterverbreitet werden. Auszüge bedürfen der Genehmigung der Physikalisch-Technischen Bundesanstalt.

*This certificate is computer generated. No signature is required. This certificate may not be reproduced other than in full. Extracts may be taken only with the permission of the Physikalisch-Technische Bundesanstalt.*

## Zertifikatsgeschichte

### History of the Certificate

| <b>Zertifikatsausgabe</b><br><i>Issue of the Certificate</i> | <b>Datum</b><br><i>Date</i> | <b>Änderungen</b><br><i>Modifications</i>       |
|--------------------------------------------------------------|-----------------------------|-------------------------------------------------|
| DE-24-NAWID-PTB013                                           | 16.04.2025                  | Erstbescheinigung<br><i>Initial certificate</i> |

Anmerkung: Diese EU-Baumusterprüfbescheinigung ist eine Neuauflage der EG-Baumusterprüfbescheinigung D05-09-024.

Remark: This EU type examination certificate is the reissue of the EC type examination certificate D05-09-024.

## Ergebnisse der Prüfung

### Conclusions of the examination

Für die in dieser Bescheinigung genannten Geräte gelten die wesentlichen Anforderungen gemäß Anhang I der Richtlinie **2014/31/EU** des Europäischen Parlaments und des Rates vom 26. Februar 2014 zur Angleichung der Rechtsvorschriften der Mitgliedstaaten betreffend die Bereitstellung nichtselbsttätiger Waagen auf dem Markt (ABl. L 96 S. 107) in der derzeit geltenden Fassung in Verbindung mit § 6 des Mess- und Eichgesetzes vom 25.07.2013 (BGBl. I S. 2722) in der derzeit geltenden Fassung und § 8 der Mess- und Eichverordnung vom 11.12.2014 (BGBl. I S. 2010) in der derzeit geltenden Fassung.

*For the instruments mentioned in this Certificate, the essential requirements according to Annex I of Directive **2014/31/EU** of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L96 S. 107) in the currently valid version in connection with Section 6 of the Measures and Verification Act of 25.07.2013 (Federal Law Gazette – BGBl. I p. 2722) in the currently valid version and Section 8 of the Measures and Verification Ordinance of 11.12.2014 (Federal Law Gazette – BGBl. I p. 2010) in the currently valid version apply.*

Für die Geräte werden folgende harmonisierte Normen bzw. normative Dokumente angewendet:

*For the instruments, the following harmonized standards or normative documents will be applied:*

- DIN EN 45501:2016-03      Metrologische Aspekte der nichtselbsttätigen Waagen; Deutsche Fassung EN 45501:2015  
*DIN EN 45501:2016-03      Metrological aspects of non-automatic weighing instruments; German version EN 45501:2015*

Für die Geräte werden zusätzlich folgende Spezifikationen angewendet:

*For the instruments, the following technical specifications will be applied additionally:*

- WELMEC 7.5 (2020)

Der nachfolgend beschriebene technische Entwurf des Messgeräts entspricht den o. g. wesentlichen Anforderungen. Mit dieser Bescheinigung ist die Berechtigung verbunden, die in Übereinstimmung mit dieser Bescheinigung gefertigten Geräte mit der Nummer dieser Bescheinigung zu versehen.

*Conclusions of the examination: The measuring instrument's technical design which is described below complies with the above-mentioned essential requirements. With this Certificate, permission is given to attach the number of this Certificate to the instruments that have been manufactured in compliance with this Certificate.*

## Die Geräte müssen folgenden Festlegungen entsprechen:

*The instruments must meet the following provisions:*

## 1 Bauartbeschreibung

### *Design of the instrument*

Nichtselbsttätige elektromechanische Waage, ausgeführt als:

*Non-automatic electromechanical weighing instrument* *Non-automatic weighing instrument, designed as:*

- Kompakte Waage einschließlich Lastaufnehmer, Wägezelle und Auswerteelektronik (analog und / oder digital)
- *Compact weighing instrument including load receptor, load cell and data processing electronics (analogue and / or digital)*

Zusätzliche kommerzielle Modellbezeichnungen der Waage sind zulässig.

*Further commercial model designations of the weighing instrument are allowed.*

### 1.1 Aufbau

#### *Construction*

Die Waage ist kompakt aufgebaut.

*The weighing instrument is of compact design.*

Folgende Varianten der Waage sind zulässig:

*Following variants of the weighing instrument are permitted:*

| Ausführung<br><i>Model</i> | Variante<br><i>Variant</i>                     | Beschreibung<br><i>Description</i>                               | Abbildung<br><i>Figure</i> |
|----------------------------|------------------------------------------------|------------------------------------------------------------------|----------------------------|
| 1                          | BIS01A<br>BIS01B<br>BIS01C<br>BIS01D<br>BIS01E | Säuglingswaage<br><i>Weighing instrument for weighing babies</i> | 1-3                        |

### 1.2 Messwertaufnehmer

#### *Measuring sensor*

Folgende Messverfahren und -wertaufnehmer sind zulässig:

*Following measuring methods and measuring sensors are permitted:*

| Ausführung<br><i>Model</i> | Beschreibung<br><i>Description</i>                             | Abbildung<br><i>Figure</i> |
|----------------------------|----------------------------------------------------------------|----------------------------|
| Flintec PB-7,5-C3          | Dehnungsmessstreifenwägezelle<br><i>Strain gauge load cell</i> | ---                        |
| Flintec PB-3,75-C3         | Dehnungsmessstreifenwägezelle<br><i>Strain gauge load cell</i> | ---                        |

### 1.3 Messwertverarbeitung

#### *Measurement value processing*

Die A/D-Wandlung, Skalierung, Ermittlung des Wägewertes sowie die weitere Datenverarbeitung und Bedienung der Waage erfolgt durch eine integrierte Auswerteelektronik.

*The A/D-conversion, scaling, determination of the weight value as well as the following data processing and operation of the weighing instrument is performed by integrated analysis electronics.*

## 1.4 Messwertanzeige

### *Indication of the measurement results*

Die Hauptanzeige ist wie folgt ausgeführt:

*The primary display is implemented as follows:*

| Typbezeichnung<br><i>Type designation</i> | Art der Anzeige<br><i>Kind of indication</i>  | Abbildung<br><i>Figure</i> |
|-------------------------------------------|-----------------------------------------------|----------------------------|
| ---                                       | 7-Segment-Anzeige<br><i>7-segment display</i> | 1                          |

## 1.5 Einrichtungen und Funktionen, die der Richtlinie unterliegen

### *Equipment and functions subject to the directive*

|                                                                                                                                                                                                     | Bezug auf<br><i>Reference to</i><br>DIN EN 45501 |   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|---|
| Einschaltnullstelleinrichtung<br><i>Initial zero-setting device</i>                                                                                                                                 | T.2.7.2.4                                        | • |
| Nullnachführeinrichtung<br><i>Zero-tracking device</i>                                                                                                                                              | T.2.7.3                                          | • |
| Halbselbsttätige Taraausgleichseinrichtung<br><i>Semi-automatic subtractive tare-balancing device</i>                                                                                               | T.2.7.4.1                                        | • |
| Nivelliereinrichtung<br><i>Leveling device</i>                                                                                                                                                      | T.2.7.1                                          | • |
| Anzeigesegmenttest beim Einschalten der Waage (alle Segmente der Anzeige leuchten kurz auf)<br><i>Display segment test on switch-on of the scale (all segments of the display briefly light up)</i> | 5.3.1                                            | • |
| Vorrichtung zur Anzeige des Eichzählerinhaltes<br><i>Device for displaying the calibration count</i>                                                                                                | ---                                              | • |

- Immer vorhanden / *Always present.*
- Optional vorhanden / *Optionally present.*

## 1.6 Technische Unterlagen

### *Technical documents*

Die zu diesem Zertifikat gehörenden technischen Unterlagen sind im zugehörigen Zertifizierungs-Dokumentensatz bei der PTB hinterlegt. Das Inhaltsverzeichnis des Zertifizierungs-Dokumentensatzes wurde dem Inhaber des Zertifikats zugeschickt.

*The technical documents relating to this Certificate are deposited in the respective Set of Certification Documents at PTB. The Table of Contents of the Set of Certification Documents was sent to the owner of the Certificate.*

## 1.7 Integrierte Einrichtungen und Funktionen, die nicht der Richtlinie unterliegen

*Integrated equipment and functions not subject to the directive*

|                                                                                                                                                                                                                 | Bezug auf<br>Reference to<br>DIN EN 45501 |   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|---|
| Manuelle Hold- und Autohold Einrichtung (aufrufbare nicht eichfähige Daueranzeige Gewichtswertes)<br><i>Manual hold and autohold device (permanent display can be invoked; not admissible for verification)</i> | ---                                       | ○ |
| Automatische Ausschaltung der Waage bei Inaktivität der Waage<br><i>Automatic switch-off function if the scale is inactive for any length of time</i>                                                           | ---                                       | ○ |
| Vorrichtung zur Anzeige des GAL-Wertes (Ersteichung)<br><i>Device for displaying the gravity factor (GAL value) (initial verification)</i>                                                                      | ---                                       | ○ |
| Einmalige GAL-Wert Einstellung nach Ersteichung vor Inbetriebnahme<br><i>One-off gravity factor setting after initial verification before setting into operation</i>                                            | ---                                       | ○ |
| Differenzfunktion (BMIF - Breast Milk Intake Function)<br><i>Difference function (BMIF - Breast Milk Intake Function)</i>                                                                                       | ---                                       | ○ |
| Mechanischer Längenmessstab<br><i>Mechanical length measuring rod</i>                                                                                                                                           | ---                                       | ○ |

- Immer vorhanden / Always present.
- Optional vorhanden / Optionally present.

## 2 Technische Daten

*Technical data*

Die Wägebereiche mit Max, Min, Eichwerten und Anzahl der Eichwerte dürfen in Anlehnung an Abschnitt 3.2 und 3.3 der DIN EN 45501 in den Grenzen gemäß nachfolgender Tabelle gewählt werden.

*The weighing ranges with Max, Min, scale intervals and number of scale intervals may be selected on basis of section 3.2 and 3.3 of DIN EN 45501 within the limits listed in the following table.*

| Variante<br>Variant                                                                                   |                     | BIS01A                                                        | BIS01B        | BIS01C        | BIS01D        | BIS01E  |
|-------------------------------------------------------------------------------------------------------|---------------------|---------------------------------------------------------------|---------------|---------------|---------------|---------|
| Genauigkeitsklasse<br>Accuracy class                                                                  |                     | III                                                           | III           | III           | III           | III     |
| Höchstlast Max <sub>1</sub> /Max <sub>2</sub><br>Maximum capacity Max <sub>1</sub> /Max <sub>2</sub>  | kg                  | 6/15                                                          | 5/12          | 7,5/20        | 7,5/15        | 15      |
| Mindestlast Min <sub>1</sub> /Min <sub>2</sub><br>Minimum capacity Min <sub>1</sub> /Min <sub>2</sub> | kg                  | 0,04/0,1                                                      | 0,04/0,1      | 0,1/0,2       | 0,1/0,2       | 0,1     |
| Anzahl n der Teilungswerte<br>Number n of scale intervals                                             |                     | ---                                                           | ---           | ---           | ---           | ≤ 3000  |
| Anzahl n <sub>i</sub> der Teilungswerte<br>Number n <sub>i</sub> of scale intervals                   |                     | ≤ 3000 / 3000                                                 | ≤ 2500 / 2400 | ≤ 1500 / 2000 | ≤ 1500 / 1500 | ---     |
| Taraausgleichsbereich (subtraktiv)<br>Tare-balancing range (subtractive)                              | • Max <sup>1)</sup> | ≤ 100 %                                                       | ≤ 100 %       | ≤ 100 %       | ≤ 100 %       | ≤ 100 % |
| Plattform<br>Platform                                                                                 |                     | Muldenförmig 615 mm x 270 mm<br>trough-shaped 615 mm x 270 mm |               |               |               |         |

- <sup>1)</sup> Für jeden Bereich bei Ein- und Mehrbereichswaagen  
*For each range of single- and multiple range instruments.*

## 2.1 Nennbetriebsbedingungen

*Rated operating conditions*

Umgebungsbedingungen und Einflussgrößen:  
*Environmental conditions and influence factors:*

|                                               |                                                                                  |
|-----------------------------------------------|----------------------------------------------------------------------------------|
| Temperaturbereich<br><i>Temperature range</i> | +10 °C / +40°C                                                                   |
| Feuchtigkeit<br><i>Humidity</i>               | bis 85 % bei 40 °C, nicht betauend<br><i>up to 85 % at 40 °C, not condensing</i> |

## 2.2 Sonstige Betriebsbedingungen

*Other operating conditions*

Keine  
*None*

## 3 Schnittstellen und Kompatibilitätsbedingungen

*Interfaces and compatibility conditions*

### 3.1 Schnittstellen

*Interfaces*

|                                                                                               |   |
|-----------------------------------------------------------------------------------------------|---|
| Schnittstelle<br><i>Interface</i>                                                             |   |
| Serielle Schnittstelle (SeSAM- oder ISIS-Bus)<br><i>Serial Interface (SeSAM- od ISIS bus)</i> | ● |
| SECA 360° Schnittstelle<br><i>SECA 360° Interface</i>                                         | ○ |

- Immer vorhanden / *Always present*
- Optional vorhanden / *Optionally present*

### 3.2 Kompatibilitätsbedingungen

*Compatibility conditions*

Bedingungen zum Anschluss von richtlinienrelevanten Einrichtungen  
*Conditions for connecting devices with regard to the Directive*

|                                                                                                                                              |   |
|----------------------------------------------------------------------------------------------------------------------------------------------|---|
| Anschließbare Einrichtungen mit Baueinheiten-Zertifikat <sup>a)</sup><br><i>Connectable devices with parts certificate <sup>a)</sup></i>     | ○ |
| Anschließbare Einrichtungen ohne Baueinheiten-Zertifikat <sup>b)</sup><br><i>Connectable devices without parts certificate <sup>b)</sup></i> | ○ |

- Immer vorhanden / *Always present*
- Optional vorhanden / *Optionally present*

- a) Das Baueinheiten-Zertifikat muss von einer benannten Stelle nach WELMEC-Leitfaden 8.8 und im Sinne dieser Richtlinie ausgestellt sein.  
*The parts certificate must be issued by a notified body according to WELMEC guide 8.8 and within this meaning of directive.*
- b) Einfache, nur Daten empfangende Druckeinrichtungen gemäß WELMEC-Leitfaden 2.10 (2021), Anhang B2.  
*Simple, only data receiving printing devices according to WELMEC 2.10 (2021), annex B2.*

## **4 Anforderungen an Produktion, Inbetriebnahme und Verwendung**

*Requirements on production, putting into use and utilisation*

### **4.1 Anforderungen an die Produktion**

*Requirements on production*

- 4.1.1 Durch besondere konstruktive Maßnahmen (Überlastsicherung, ausreichend hohe Nennlast der Wägezellen o. ä.) ist eine Überlastung der Wägezellen zu verhindern.  
*The load cells shall be protected against overloading by special constructional means (overload protection, sufficiently high nominal load of the load cells etc.).*

### **4.2 Anforderungen an die Inbetriebnahme**

*Requirements on putting into use*

- 4.2.1 Prüfung der Identifizierbarkeit der Waage nach Abschnitt 5.3  
*Examination of identifiability of the weighing instrument according to section 5.3*
- 4.2.2 Prüfungen nach Abschnitt 5.4  
*Examination according to section 5.4*
- 4.2.3 Prüfung der Kennzeichnung gemäß Abschnitt 7  
*Checking the designations according to section 7*
- 4.2.4 Prüfung, ob die Anforderungen an die Produktion gemäß Abschnitt 4.1 erfüllt werden.  
*Checking the requirements on production according to section 4.1.*

### **4.3 Anforderungen an die Verwendung**

*Requirements for consistent utilisation*

Es gelten die Angaben der Bedienungsanleitung.  
*The information of the user's manual has to be applied.*

## 5 Kontrolle in Betrieb befindlicher Geräte

*Checking of instruments which are in operation*

### 5.1 Unterlagen für die Prüfung

*Documents required for the test*

- Kopie dieser Baumusterprüfbescheinigung  
*Copy of this type examination certificate*
- Handbuch/Bedienungsanleitung.  
*Handbook/user's manual.*
- Falls anwendbar, Kopien von Baueinheitenzertifikaten.  
*If applicable, copies of parts certificates.*

### 5.2 Spezielle Prüfeinrichtungen oder Software

*Special test facilities or software*

Keine  
*None*

### 5.3 Identifizierung

*Identification*

Gemäß Abschnitt 1 und Abbildungen in Abschnitt 8.  
*According to section 1 and figures in section 8.*  
Es gelten die Angaben der Bedienungsanleitung.  
*The information of the user's manual has to be applied.*

#### 5.3.1 Software-Identifikation

*Software identification*

Für die unterschiedlichen Ausführungen der Waage zulässige Software-Versionen:  
*Software versions permitted for different implementations of the weighing instrument:*

| Typ<br><i>Type</i>                             | Software-ID <sup>a)</sup><br><i>Software ID <sup>a)</sup></i> | Checksumme<br><i>Checksum</i> |
|------------------------------------------------|---------------------------------------------------------------|-------------------------------|
| BIS01A<br>BIS01B<br>BIS01C<br>BIS01D<br>BIS01E | 01.yy                                                         | ---                           |

- <sup>a)</sup> Der Platzhalter „yy“ steht für eine beliebig lange alphanumerische Zeichenkette, die für Releases der Software-Version steht, die nicht richtlinienrelevante Änderungen beschreiben.  
*The placeholder “yy” stands for a random alphanumeric string that stands for releases of the software version which describe modifications not relevant regarding the Directive.*

#### 5.3.2 Kontrolle der Software-Identifikation

*Verification of software identification*

Es gelten die Angaben der Bedienungsanleitung.  
*The information of the user's manual has to be applied.*

## **5.4 Kalibrier-, Justier- und Prüfverfahren**

*Calibration-/adjustment procedure/examinations*

Besondere Kalibrierungen und Justierungen sind bei der Inbetriebnahme nicht erforderlich.

*Special calibrations and adjustments are not required.*

### **5.4.1 Messtechnische Prüfungen**

*Metrological tests*

- Gemäß OIML Empfehlung R 76-1, Abschnitt 8.3.3.  
*According to OIML Recommendation R 76-1, section 8.3.3.*

## **6 Sicherungsmaßnahmen**

*Security measures*

### **6.1 Mechanische Siegel**

*Mechanical seals*

Mechanische Siegel sind an folgenden Stellen anzubringen:

*Mechanical seals have to be applied to the following locations:*

- Gemäß Abbildungen 1 bis 3  
*According to figures 1 to 3*

### **6.2 Elektronische Siegel**

*Electronic seals*

Aufruf des Ereigniszählers:

*Calling-up the event counter:*

Siehe Bedienungsanleitung

*See user's manual*

## **7 Kennzeichnungen und Aufschriften**

*Labelling and inscriptions*

### **7.1 Informationen, die dem Gerät beizufügen sind**

*Information to be enclosed with the instrument*

Bedienungsanleitung

*User's manual*

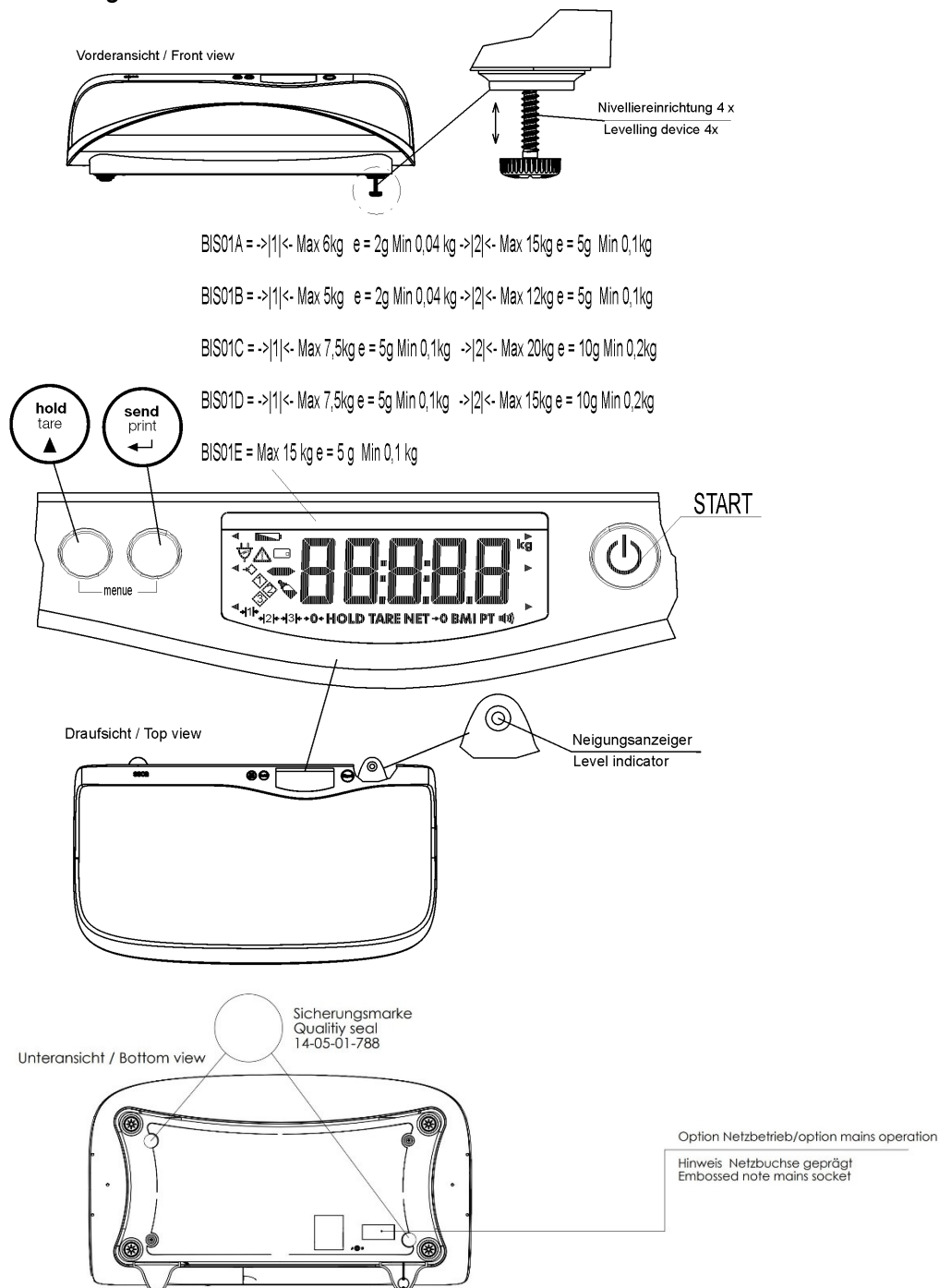
### **7.2 Kennzeichen und Aufschriften**

*Markings and inscriptions*

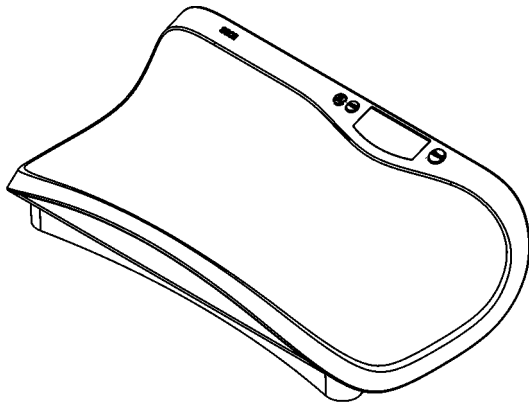
Das CE-Kennzeichen und die Aufschriften nach Richtlinie sind auf dem Kennzeichnungsschild angebracht. Das Kennzeichnungsschild befindet sich auf der Rückseite der Waage.

*The CE mark and the inscription as per the Directive are located on the data plate. The data plate is placed on the backside of the weighing instrument.*

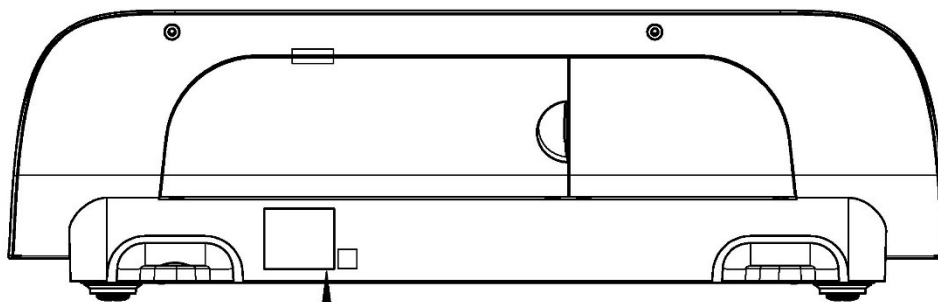
## 8 Abbildungen Figures



**Abbildung 1:** Anordnung der Schilder und Sicherungsmarken, Typen BIS01A bis BIS01E  
**Figure 1:** Positioning of the descriptive markings and the securing marks, types BIS01A to BIS01E



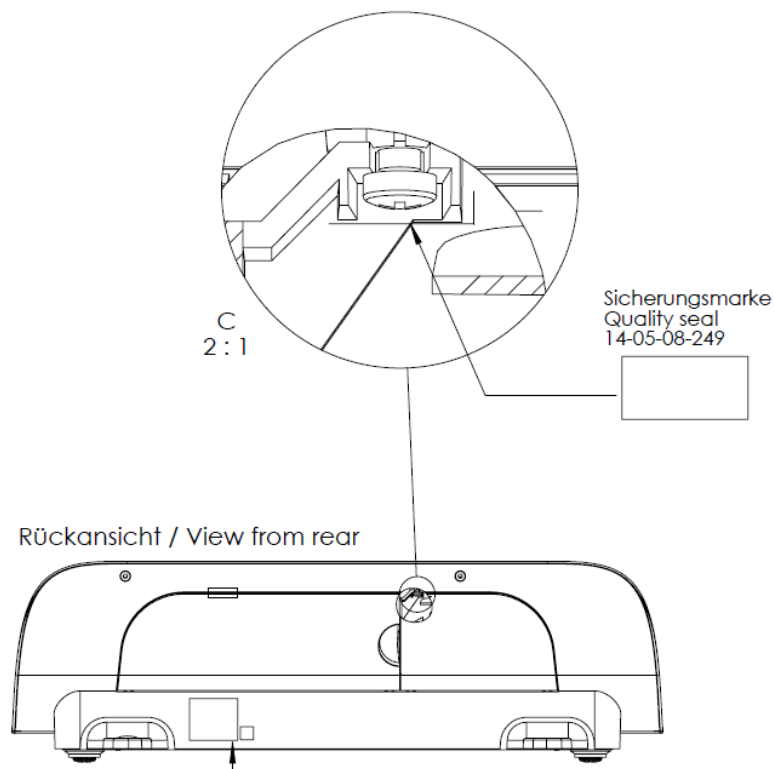
Rückansicht / View from rear



Typenschild  
Descriptive plate

Eichzählermarke  
Mark with checksum

**Abbildung 2:** Anordnung der Schilder und Sicherungsmarken, Typen BIS01A bis BIS01E  
**Figure 2:** Positioning of the descriptive markings and the securing marks, types BIS01A to BIS01E



**Abbildung 3:**  
**Figure 3:**

Sicherung der Serviceklappe innerhalb des Batteriefachs, Typen BIS01A bis BIS01E

Securing of the service cover within the battery lot, types BIS01A to BIS01E