



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 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.

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22089 Hamburg**

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Geschäftsführung:
Walter Reithmaier (Sprecher)
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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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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,

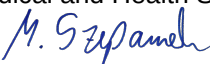
by the 20 Mar 2023 for the relevant devices.

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,

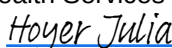
TÜV SÜD Product Service GmbH
Medical and Health Services

Signatur: 

E-Mail: Martin.Szepannek@tuvsud.com

Martin Szepannek
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

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

E-Mail: Julia.Hoyer@tuvsud.com

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 (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
seca 201 / 2011717009 seca 201 / 2011817009 seca 203 / 2031717009 (401203000000000000050QL)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 206 / 2061717009 seca 206 / 2061817139 (401203000000000000055QW)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 207 / 2071714008 seca 207 / 2071814008 seca 210 / 2101721004 seca 210 / 2101821004 seca 416 / 4161721009 seca 416 / 4161821009 seca 417 / 4171721009 seca 417 / 4171821009 (401203000000000000031QG)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 212 / 2121717009 seca 212 / 2121817009 (401203000000000000051QN)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 213 / 2131721009 seca 213 / 2131821009 seca 213 / 2131721759 seca 216 / 2161814009 seca 217 / 2171721009 seca 217 / 2171821009 seca 222 / 2221714008 seca 222 / 2221814008 (401203000000000000030QE)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 220 / 2201714003 seca 220 / 2201814003 seca 223 / 2231717998 seca 223 / 2231814998 seca 224 / 2241714004 (401203000000000000036QS)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 232 n / 2321717008 seca 232 / 2321817008 seca 233 / 2331714004 seca 233 / 2331814004 (401203000000000000043QP)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068;



Device name / Reference (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
		☐ Identification of the corresponding device under MDD/AIMDD	NB 0123
seca 234 / 2341717009 seca 234 / 2341817009 (401203000000000000056QY)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 264 / 2641900099 seca 264 / 2641900009 seca 274 / 2741900099 seca 274 / 2741900009 (401203000000000000041QK)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 284 / 2841000109 seca 284 / 2841300109 seca 284 / 2841310109 seca 285 / 2857000009 seca 285 / 2857000199 seca 285 / 2857000289 seca 285 / 2857000649 seca 285 / 2857000669 (401203000000000000057R2)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 286 / 2861000009 seca 286 / 2861300009 seca 286 / 2861300209 seca 286 / 2861300909 seca 286 r / 2866900209 seca 287 / 2877000009 seca 287 / 2877000099 seca 287 / 2877000229 seca 287 / 2877000289 seca 287 / 2877000649 seca 287 / 2877000799 seca 287 / 2877000889 seca 287 / 2877000899 (401203000000000000058R4)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 310 / 3101017654 (401203000000000000035QQ)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 334 / 3341021008 seca 334 / 3341321008 seca 334 / 3341321619 (401203000000000000047QX)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 333 i / 3331021004 seca 333 i / 3331021009 seca 333 i / 3337321009 seca 336 / 3367021008 seca 336 / 3367021098 seca 336 / 3367021223	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068;



Device name / Reference (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
seca 336 / 3367021283 seca 336 / 3367021438 seca 336 / 3367021644 seca 336 / 3367021668 seca 336 / 3367021688 seca 336 i / 3367321009 seca 336 i / 3367321099 seca 336 i / 3367321229 seca 336 i / 3367321289 seca 336 i / 3367321439 seca 336 i / 3367321649 seca 336 i / 3367321669 seca 336 i / 3367321689 (401203000000000000042QM)		☐ Identification of the corresponding device under MDD/AIMDD	NB 0123
seca 374 / 3741021004 seca 374 / 3741321004 seca 376 / 3767021008 seca 376 / 3767021098 seca 376 / 3767021228 seca 376 / 3767021288 seca 376 / 3767021438 seca 376 / 3767021649 seca 376 / 3767021668 seca 376 / 3767021688 seca 376 / 3767021259 seca 376 / 3767021128 (401203000000000000046QV)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 384 / 3847017009 seca 384 / 3847017099 seca 384 / 3847017229 seca 384 / 3847017649 seca 384 / 3847017669 seca 384 / 3847017689 seca 384 / 3847017259 seca 384 / 3847017129 seca 385 / 3857017094 seca 385 / 3857017124 seca 834 / 8347017094 (401203000000000000037QU)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 634 / 6341321008 seca 634 / 6341921024 seca 635 / 6357021004 seca 635 / 6357021094 seca 635 / 6357021224 seca 635 / 6357021284 seca 635 / 6357021649 seca 635 r / 6357021999 seca 644 / 6441021108 seca 644 / 6441321108 seca 645 / 6457021003 seca 645 / 6457021193 seca 645 / 6457021223 seca 645 / 6457021283 seca 645 / 6457021649 seca 656 / 6561321103 seca 657 / 6577021003 seca 657 / 6577021193 seca 657 / 6577021223 seca 657 / 6577021283 seca 657 / 6577021644	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123



Device name / Reference (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
seca 657 r / 6577921193 seca 664 / 6641321103 seca 665 / 6657021003 seca 665 / 6657021193 seca 665 / 6657021223 seca 665 / 6657021283 seca 665 / 6657021433 seca 665 / 6657021644 seca 667 / 6677021619 seca 667 / 6677021629 seca 667 / 6677021759 seca 674 / 6741321103 seca 675 / 6757021003 seca 675 / 6757021193 seca 675 / 6757021223 seca 675 / 6757021283 seca 675 / 6757021433 seca 675 / 6757021644 seca 676 / 6761021108 seca 676 / 6761321108 seca 676 r / 6761321994 seca 677 / 6777021008 seca 677 / 6777021198 seca 677 / 6777021228 seca 677 / 6777021288 seca 677 / 6777021438 seca 677 / 6777021644 seca 677 r / 6777021994 seca 684 / 6841321107 seca 684 r / 6841321994 seca 685 / 6857021003 seca 685 / 6857021193 seca 685 / 6857021223 seca 685 / 6857021283 seca 685 / 6857021644 seca 685 r / 6857021994 (4012030000000000000039QY)			
seca 700 s / 7001321993 seca 700 s / 7001121993 seca 700 s / 7001021993 seca 700 s / 7001021933 seca 711 s / 7117021998 (4012030000000000000060QP)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 700 / 7001321008 seca 700 / 7001121008 seca 700 / 7001021658 seca 700 / 7001021008 seca 711 / 7117021004 (4012030000000000000028QT)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 703 s / 7031021997 seca 703 s / 7031321997 seca 703 s / 7037821004 seca 704 s / 7047721093 seca 704 s / 7047721123 (4012030000000000000061QR)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 703 / 7031321007 seca 704 / 7047021008 seca 704 / 7047021098 seca 704 / 7047021228	☐ N/A or	☒ N/A or	☐ N/A or



Device name / Reference (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
seca 704 / 7047021288 seca 704 / 7047021438 seca 704 / 7047021649 seca 704 / 7047021668 seca 704 / 7047021688 seca 704 r / 7047021999 seca 704 r / 7047921129 seca 704 / 7047021259 seca 704 / 7047021128 (401203000000000000038QW)	☒ Class I devices with a measuring function	☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 725 / 7251021004 seca 725 / 7251021654 seca 725 / 7251021944 seca 745 / 7457021004 (401203000000000000027QR)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 755 / 7551021004 seca 755 / 7551321004 seca 755 / 7551421004 seca 756 / 7567021004 seca 786 / 7862021004 (401203000000000000053QS)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 755 s / 7551021998 seca 755 s / 7551321998 seca 756 s / 7567021998 seca 786 s / 7862021998 (401203000000000000063QV)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 727 / 7271321868 seca 757 / 7577021008 seca 757 / 7577021124 seca 757 / 7577021228 seca 757 / 7577021288 seca 757 / 7577021434 seca 757 / 7577021644 seca 757 / 7577021664 seca 757 / 7577021698 (401203000000000000048QZ)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 750 / 7501017008 seca 750 / 7501019008 seca 750 / 7501119008 seca 750 / 7501319003 seca 760 / 7601019004 seca 760 / 7601025004 seca 760 / 7601026008 seca 760 / 7601028008 seca 760 / 7601029008 seca 760 / 7601419004 seca 760 / 7601425004 seca 760 / 7601426004 seca 760 / 7601428004 seca 760 / 7601429004 seca 761 / 7617019008 seca 761 / 7617019128 seca 762 / 7621019008 seca 762 / 7621319004	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123



Device name / Reference (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
(401203000000000000054QU) seca 769 / 7691321004 seca 799 / 7997021009 seca 799 / 7997021099 seca 799 / 7997021229 seca 799 / 7997021289 seca 799 / 7997021439 seca 799 / 7997021649 seca 799 / 7997021669 seca 799 / 7997021689 seca 799 / 7997021259 seca 799 / 7997021129	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
(401203000000000000052QQ) seca 769 s / 7691321998 seca 799 s / 7997021304 (401203000000000000062QT)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 777 / 7771721004 seca 777 / 7771821004 seca 787 / 7871721004 seca 787 / 7871821004 seca 797 / 7971721004 seca 797 / 7971821004 (401203000000000000059R6)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 869 / 8691021004 seca 869 / 8691321004 seca 874 / 8741021653 seca 874 / 8741021714 seca 874 / 8741321009 seca 874 dr / 8741341109 seca 874 dr / 8741341259 seca 874 dr / 8741341389 seca 874 dr / 8741341399 seca 874 dr / 8742721654 seca 875 / 8757021124 seca 875 / 8757021289 seca 875 / 8757021094 seca 876 / 8761321004 seca 877 / 8777021004 seca 877 / 8777021094 seca 877 / 8777021224 seca 877 / 8777021434 seca 877 / 8777021649 seca 877 / 8777021664 seca 877 / 8777021684 seca 877 / 8777021259 seca 877 / 8777021124 seca 878 / 8787021009 seca 878 / 8787021099 seca 878 / 8787021229 seca 878 / 8787021649 seca 878 / 8787021129 seca 878 dr / 8787041009 seca 878 dr / 8787041019 seca 878 dr / 8787041099 seca 878 dr / 8787041119 seca 878 dr / 8787041219 seca 878 dr / 8787041229	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123



Device name / Reference (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
seca 878 dr / 8787041259 seca 878 dr / 8787041289 seca 878 dr / 8787041319 seca 878 dr / 8787041389 seca 878 dr / 8787041419 seca 878 dr / 8787041429 seca 878 dr / 8787041439 seca 878 dr / 8787041649 seca 878 dr / 8787041669 seca 878 dr / 8787041689 seca 878 dr / 8787041699 seca 878 dr / 8787041129 seca 899 / 8997021004 seca 899 / 8997021094 seca 899 / 8997021224 seca 899 / 8997021284 seca 899 / 8997021649 seca 899 / 8787041129 (4012030000000000000029QV)			
seca 954 / 9541309007 seca 954 r / 9541309997 seca 955 / 9557021124 seca 955 / 9557021124 seca 957 / 9577021094 seca 957 / 9577021004 seca 957 / 9577021759 seca 959 / 9597021002 seca 959 / 9597021092 seca 959 / 9597021226 seca 959 / 9597021286 seca 959 / 9597021439 seca 959 / 9597021649 seca 959 / 9597021669 seca 959 / 9597021689 seca 959 / 9597021929 seca 959 r / 9597921929 (4012030000000000000049R3)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; NB 0123
seca 952 / 9521309009 seca 956 / 9567021009 seca 956 / 9567021099 seca 956 / 9567021229 seca 956 / 9567021289 seca 956 / 9567021439 seca 956 / 9567021649 seca 956 / 9567021669 seca 956 / 9567021689 seca 956 / 9567021259 seca 956 / 9567021129 (4012030000000000000040QH)	☐ N/A or ☒ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: G3M 18 03 12163 068; 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.	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☒ N/A or ☐ Certification as follows: Certificate #: Certificate #: or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# 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.:

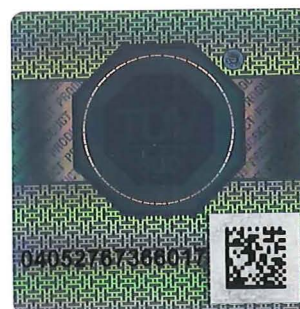
713128921

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

Typbezeichnung:
Type designation:

COS02A

Nr. der Bescheinigung:
Certificate No.:

DE-24-NAWID-PTB015

Gültig bis:
Valid until:

05.03.2035

Anzahl der Seiten:
Number of pages:

11

Geschäftszeichen:
Reference No.:

KBS 2-4.3-06.02.03/0368#0001

Notifizierte Stelle:
Notified Body:

0102

Zertifizierung:
Certification:

Braunschweig, 06.03.2025

Bewertung:
Evaluation:

Im Auftrag
On behalf of PTB

Siegel
Seal

Im Auftrag
On behalf of PTB

Dr.-Ing. Oliver Mack

Sven Vasterling



Physikalisch-Technische Bundesanstalt
Nationales Metrologieinstitut

digital gesiegelt
Physikalisch-Technische Bundesanstalt
06.03.2025
14:49:22 +01

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.

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Zertifikatsgeschichte

History of the Certificate

Zertifikatsausgabe <i>Issue of the Certificate</i>	Datum <i>Date</i>	Änderungen <i>Modifications</i>
DE-24-NAWID-PTB015	06.03.2025	Erstbescheinigung <i>Initial certificate</i>

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

Ggf. vorhandene Abweichungen von den harmonisierten Normen bzw. normativen Dokumenten sind in Abschnitt 1.5 festgelegt.

Potential deviations from harmonized standards or normative documents are specified in paragraph 1.5.

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 mechanische Waage, ausgeführt als:

Non-automatic mechanical weighing instrument, designed as:

- Personenwaage zur Verwendung im Gesundheitsbereich und im Bereich der Heilkunde
- *Personal scales for use in the health sector and in the field of medicine*

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.

Ausführung <i>Model</i>	Beschreibung <i>Description</i>	Abbildung <i>Figure</i>
COS02A	Nichtselbsteinspielende Waage <i>Non-self-adjusting weighing instrument</i>	1

1.2 Messwertaufnehmer

Measuring sensor

Folgende Messverfahren und -wertaufnehmer sind zulässig:

Following measuring methods and measuring sensors are permitted:

Ausführung <i>Model</i>	Beschreibung <i>Description</i>	Abbildung <i>Figure</i>
COS02A	Waage mit offener Laufgewichtseinrichtung als Auswä- geeinrichtung <i>Weighing instrument with open running weight device as weighing device</i>	2

1.3 Messwertverarbeitung

Measurement value processing

Keine

None

1.4 Messwertanzeige

Indication of the measurement results

Die Hauptanzeige ist wie folgt ausgeführt:

The primary display is implemented as follows:

Ausführung <i>Model</i>	Art der Anzeige <i>Kind of indication</i>	Abbildung <i>Figure</i>
COS02A	Offene Laufgewichtseinrichtung mit bezifferter Skale <i>Open barrel weight device with numbered scale</i>	2

1.5 Einrichtungen und Funktionen, die der Richtlinie unterliegen

Equipment and functions subject to the directive

	Bezug auf <i>Reference to</i> DIN EN 45501	
Nivelliereinrichtung <i>Leveling device</i>	T.2.7.1	•
Schrägstellung <i>Inclination</i>	3.9.1.1	•
Nichtselbsttätige Nullstelleinrichtung <i>Non-automatic zero-setting device</i>	T.2.7.2.1	•
Feststelleinrichtung <i>Locking device</i>	T.2.7.6	•

- 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

Die Waage kann optional mit einem Messstab zur Körperlängenbestimmung ausgestattet sein.

The weighing instrument can optionally be equipped with a measuring rod for determining body length.

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.

Ausführung <i>Model</i>		COS02A
Genauigkeitsklasse <i>Accuracy class</i>		III
Mindestlast Min <i>Minimum load Min</i>	kg	2
Höchstlast Max <i>Maximum capacity Max</i>	kg	220
Eichwert e <i>Verification scale interval e</i>	kg	0,1
Anzahl der Eichwerte <i>Number of verification scale intervals</i>		≤ 2.200
Wiegeplattform (im Mittel) <i>Weighing platform (on average)</i>	mm	308 x 345
Übersetzungsverhältnis <i>Gear ratio</i>		1:33

2.1 Nennbetriebsbedingungen

Rated operating conditions

Umgebungsbedingungen und Einflussgrößen:

Environmental conditions and influence factors:

Temperaturbereich <i>Temperature range</i>	+10°C / +40°C
Feuchtigkeit <i>Humidity</i>	bis 85% bei 40°C, nicht betauend <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

Keine

None

3.2 Kompatibilitätsbedingungen

Compatibility conditions

Keine

None

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 ist eine Überlastung der Waage zu verhindern. (Überlastsicherung)

Special construction must be taken to prevent the weighing instrument from being overloaded. (overload protection)

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.

5.3.1 Software-Identifikation

Software identification

Keine
None

5.3.2 Kontrolle der Software-Identifikation

Verification of software identification

Keine
None

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.

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

6 Sicherungsmaßnahmen

Security measures

6.1 Mechanische Siegel

Mechanical seals

Mechanische Siegel sind an folgenden Stellen anzubringen (siehe Abbildungen 2-4).
Mechanical seals have to be applied to the following locations (see figure 2-4).

6.2 Elektronische Siegel

Electronic seals

Keine
None

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 am Säulenfuß (siehe Abbildung 3).

The CE mark and the inscription as per the Directive are located on the data plate. The data plate is placed on column base (see figure 3).

8 **Abbildungen**

Figures



Abbildung 1:
Figure 1:

Waage COS02A
Weighing instrument COS02A

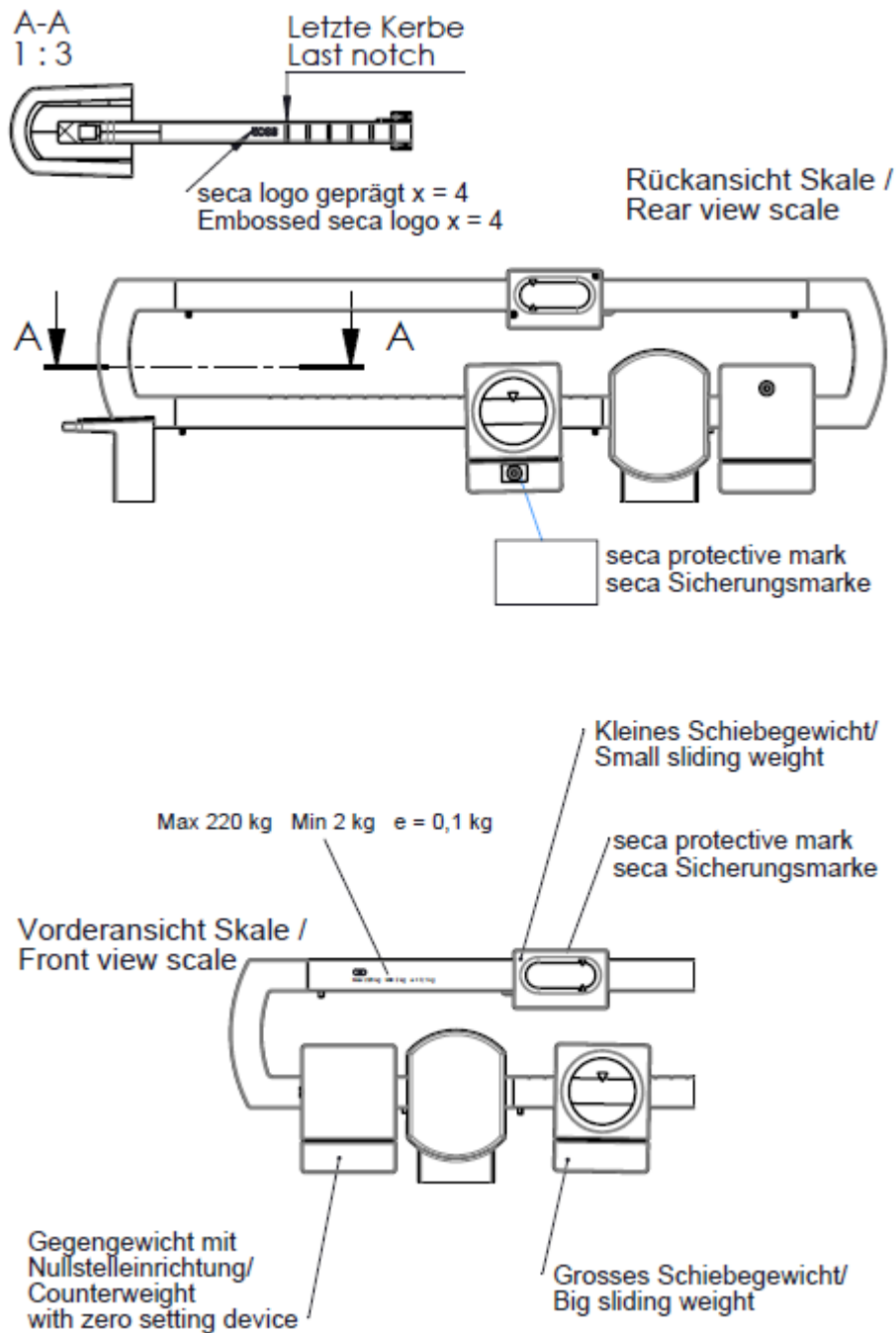


Abbildung 2: Laufgewichtseinrichtung als Auswägeeinrichtung
Figure 2: open running weight device as weighing device

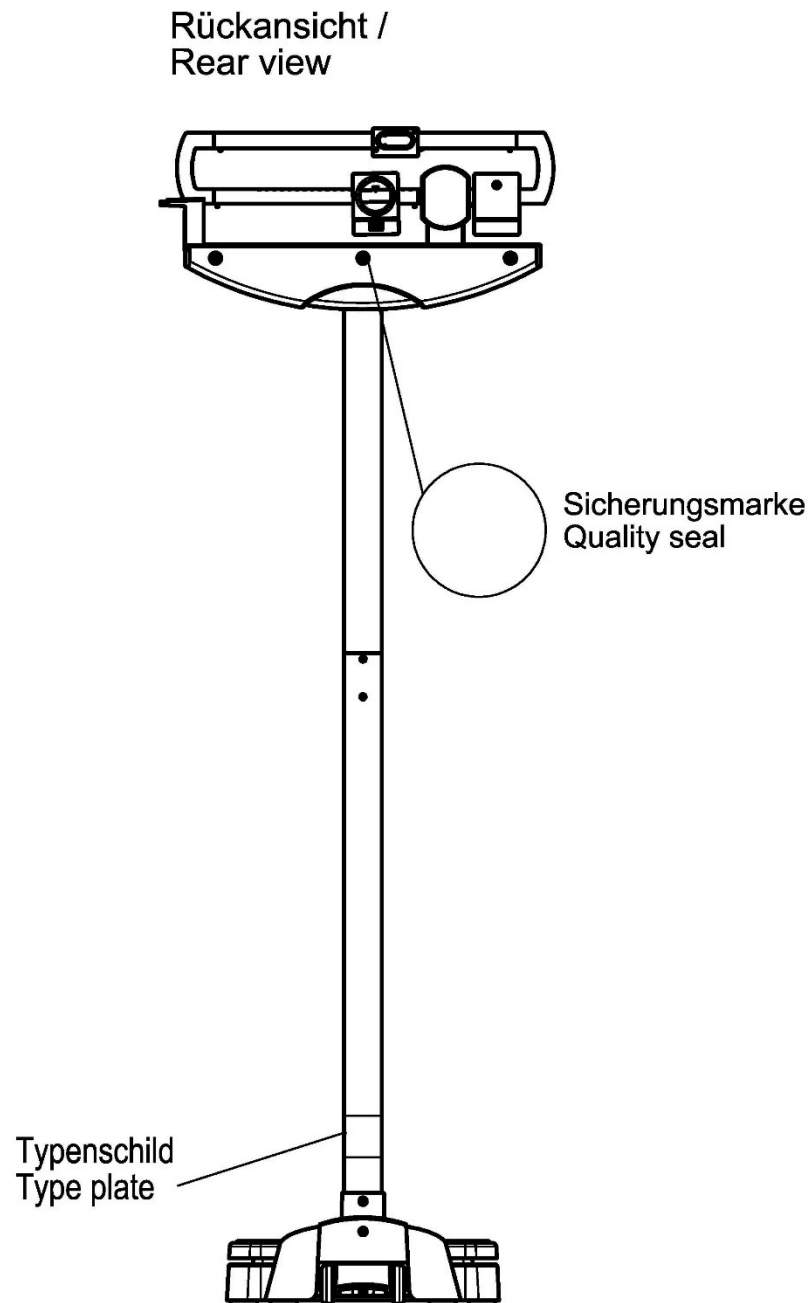


Abbildung 3: Kennzeichen und Aufschriften
Figure 3: Labelling and inscriptions

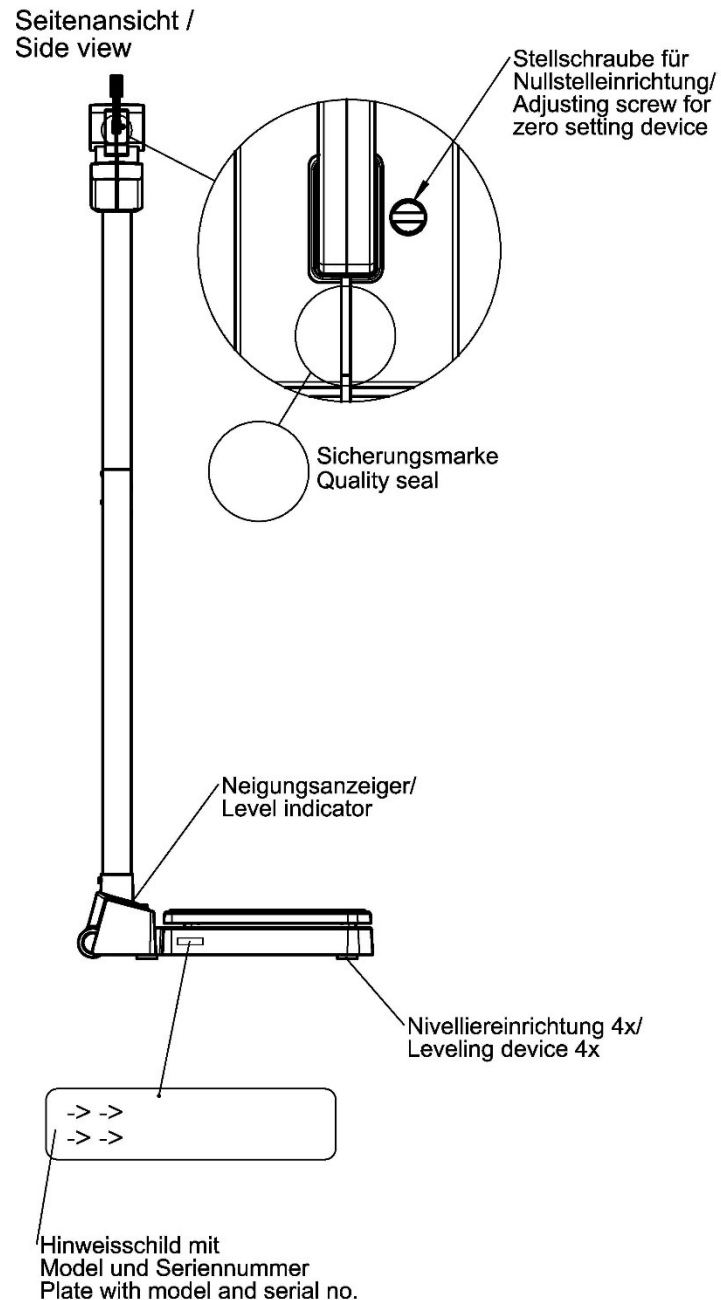


Abbildung 4: Seitenansicht der Waage
Figure 4: Side view of the weighing instrument