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

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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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SRN: DE-MF-000005469

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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

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

Julia Hoyer
Head of Certification Body - Deputy

Product Service

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 I / 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	☐ 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** **(401203000000000000039QY)**			
seca 700 s / 7001321993 **seca 700 s / 7001121993** **seca 700 s / 7001021993** **seca 700 s / 7001021933** **seca 711 s / 7117021998** **(401203000000000000060QP)**	☐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** **(401203000000000000028QT)**	☐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** **(401203000000000000061QR)**	☐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
(4012030000000000000054QU)			
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** **(4012030000000000000052QQ)**	☐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 769 s / 7691321998 **seca 799 s / 7997021304** **(4012030000000000000062QT)**	☐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** **(4012030000000000000059R6)**	☐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** **(401203000000000000029QV)**			
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** **(401203000000000000049R3)**	☐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** **(401203000000000000040QH)**	☐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

Product Service

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

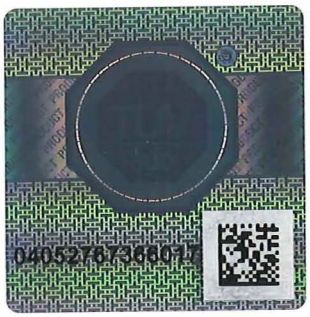
Product Category(ies):

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

TÜV®

Physikalisch-Technische Bundesanstalt
Nationales Metrologieinstitut

KBS
Konformitätsbewertungsstelle

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

PHYSIKALISCH-TECHNISCHE BUNDESANSTALT 72

R3-027579

Zertifikatsgeschichte

History of the Certificate

Zertifikats-Ausgabe *Issue of the Certificate*	**Datum** *Date*	**Änderungen** *Modifications*
DE-M-AQ-PTB123	20.04.2016	Erstbescheinigung *Initial certificate* (bislang Zertifikat mit der Registrier-Nr. 01.02-05 der Hessischen Eichdirektion), Umstellung von 2009/23/EG auf 2014/31/EU *(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, Verlängerung der Gültigkeit um 3 Jahre *1st reapproval, prolongation for another 3 years*
DE-M-AQ-PTB123, Revision 2	18.11.2020	Revision, Ergänzung Standort Pinghu/ China *Revision, completion site Pinghu/ China*
DE-M-AQ-PTB123, Revision 3	27.08.2021	2. Reanerkennung, Streichung Standort Hangzhou/ China, Verlängerung der Gültigkeit um 3 Jahre *2nd reapproval, prolongation for another 3 years*
DE-M-AQ-PTB123, Revision 4	27.08.2024	3. Reanerkennung, Verlängerung der Gültigkeit um 3 Jahre *3rd reapproval, prolongation for another 3 years*

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 (ABl 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 (ABl 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
Messgeräteart: *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
Messgeräteart: *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 Type Examination Certificate No CH-W1-14015-01_EN Translation

Applicant	**seca gmbh & co. kg** Hammer Steindamm 3-25 22089 Hamburg Germany
Requirements	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; Ordinance of the FDJP of 16 April 2004 on Non-Automatic Weighing Instruments (SR 941.213). Conformity of superseded standard: EN 45501 Edition 2015.
Type of instrument	**Non-automatic mechanical scale**
Type designation	**FLS02A**
Accuracy class(es)	(IIII)
Characteristics	Max = 150 kg e = 1 kg n = 150 Min = 10 kg
Certificate valid until	10 April 2034
Notified body	Conformity Evaluation Body METAS-Cert Nr. 1259

3003 Berne-Wabern, 11 July 2024

Approved by	Gulian Couvreur, Head of sector METAS-Cert

This certificate is a translation. In case of equivocality, the content from the original certificate is decisive
The present revision of this certificate is the only valid and replaces all previous revisions.
This document is only valid and reviewable in its electronic form.
Please observe the information given on www.metas.ch/ecert

METAS
Lindenweg 50, 3003 Bern-Wabern, Switzerland, phone +41 58 387 01 11, www.metas.ch

Annex to the EU Type Examination Certificate No CH-W1-14015-01_EN

1 Name and type of instrument

Non-automatic mechanical scale for medical usage type FLS02A.

2 Type description

The Type corresponds with the requirements of EN 45501:2015 and OIML R-76-1:2006.

2.1 Construction

2.1.1 Mechanical

With the FLS02A a weight is compensated over a lever work with a weighing spring. The spring excursion is transmitted to the display via a bell crank lever, consisting in a rack and a pinion. The non-automatic zero-setting device is externally operated by a knob and produces a change of the contact point of the weighing spring. A change of the pre-tension of the spring for the adjustment of the weighing instrument is possible, but can only be performed with a special tool. A levelling or locking device is not available.

2.2 Permitted functions and devices

- Non-automatic zero-setting device (T.2.7.2.1)

3 Technical data

3.1 Weighing instrument

Table 1

Accuracy class	(IIII)
Max	150 kg
e	1 kg
n	150
Temperature range	10 °C / 40 °C
Platform size	260 x 260 mm
Amount of spring loops	6.5
Mean loop cross section	Ø 18.65 mm
Wire cross section	Ø 2.5 mm
Spring rate in mounted condition	9.7 N/mm

3.2 Documentation

All descriptive documents and drawings used for the conformity assessment are deposited with METAS-Cert and listed in the document *"List of essential reference documents for type examination"*.

4 Interfaces and peripheral devices

None

5 Conditions for market introduction

- The type examination certificate is valid only for non-automatic weighing instruments

5.1 Legends

The weighing instrument must bear following indications:

5.1.1 Type Plate

- Manufacturer’s mark or name
- Manufacturer’s address
- Type designation and serial number of the instrument
- Metrological CE conformity marking
- Number of the type examination certificate
- Accuracy Class
- Metrological data (Max, Min, e =)
- Temperature range (if differs from -10 °C / +40 °C)

And additional markings as required by the Directive 2014/31/EU Annex III.

The number of Type Examination Certificate on the descriptive plate can be written without the revision number as follows: **CH-W1-14015.**

The type plate consists in a support that is auto destructive or that can be sealed by a securing sticker.

6 Requirements for production, commissioning and utilization

- Documents required: EU type-examination certificate, operating manual, declaration of conformity. Copies of the test certificates of modules and peripheral devices if applicable.
- The weighing instruments can be tested at the place of use or on any other place, therefore the requirements of Annex II, point 7 of the Directive 2014/31/EU must be respected. If the weighing instrument is not tested at the place of use, the place or gravity zone must figure on the type shield. This is not applicable for weighing instruments with internal span adjustment device.

7 Control of devices in operation

7.1 Test documents

See the assembly and operating instructions

7.2 Testing equipment

For the verification standard weights with a valid calibration and with five times better accuracy than the weighing instrument shall be used.

7.3 Identification

The type designation should be taken from the type plate.

7.4 Metrological test

The metrological tests must be carried out according to national applicable regulations.

8 Official stamps and conformity markings

Sealing marks (self-adhesive sticker or seal) must be attached to following locations

- On the border of the type plate (if the type plate is not self-destructive)

The safety plates on the back of the scale (Figure 5) prevent it from opening and must be intact, so an additional safety device is not necessary.

9 EU conformity mark and descriptive plate

The mark of EU conformity and the metrology marking (the metrology CE-marking signifies conformity with the essential requirements of Directive 2014/31/EU) have to be placed on the descriptive plate (Figure 4)

10 Certificate history

Issue	Date	Description
CH-W1-14015-00	11.04.2014	- First Certification
CH-W1-14015-01	11.07.2024	- Recertification

Note: All revisions can be found on www.metas.ch/cs

11 Pictures and drawings

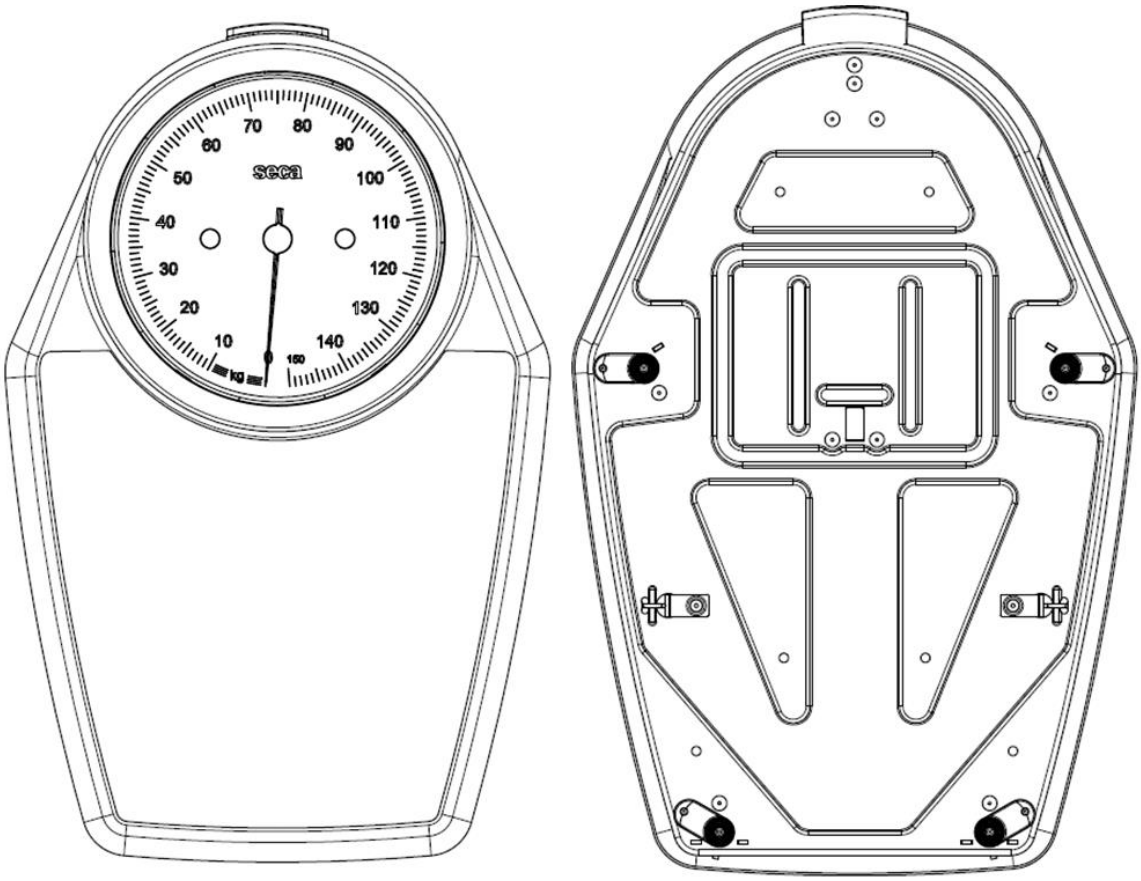


Figure 1: front and back side of the weighing instrument

Figure 2: back side with type plate and rivets

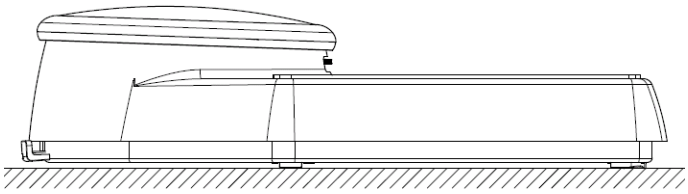


Figure 3: side view

Figure 4: example of a type plate

Figure 5: rivet securing plate

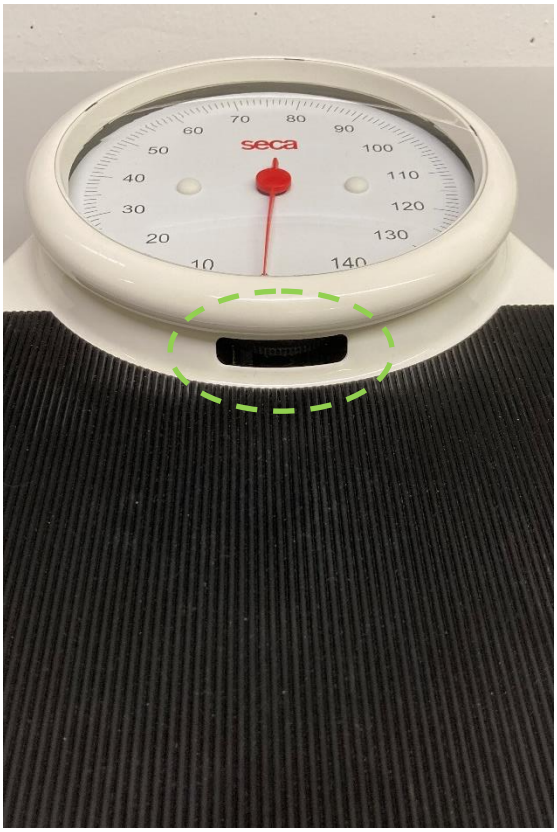


Figure 6: front view with zero setting device

Figure 7: non-automatic zero setting device