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

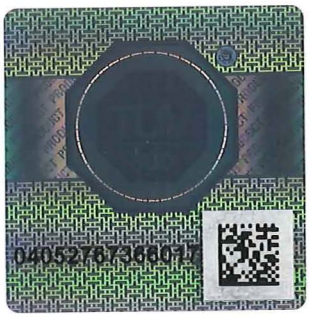
Product Category(ies):

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®

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.

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

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