



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.

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

**SRN: DE-MF-000005469**

Sitz: München  
Handelsregister München HRB 85742  
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USt-IdNr. DE129484267  
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unter [www.tuvsud.com/impressum](http://www.tuvsud.com/impressum)

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Geschäftsführung:  
Walter Reithmaier (Sprecher)  
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**TÜV®**

TÜV SÜD Product Service GmbH  
Niederlassung München

Ridlerstraße 65  
80339 München  
Deutschland



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,

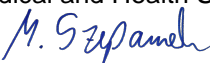
by the 20 Mar 2023 for the relevant devices.

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

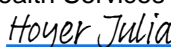
**Signatur:** 

**E-Mail:** [Martin.Szepannek@tuvsud.com](mailto:Martin.Szepannek@tuvsud.com)

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Martin Szepannek  
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH  
Medical and Health Services

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

**E-Mail:** [Julia.Hoyer@tuvsud.com](mailto:Julia.Hoyer@tuvsud.com)

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Julia Hoyer  
Head of Certification Body - Deputy



## ATTACHMENT

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

Device name / Reference (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  (40120300000000000050QL)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Certification as follows: G3M 18 03 12163 068; NB 0123
seca 206 / 2061717009 seca 206 / 2061817139  (40120300000000000055QW)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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  (40120300000000000031QG)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Certification as follows: G3M 18 03 12163 068; NB 0123
seca 212 / 2121717009 seca 212 / 2121817009  (40120300000000000051QN)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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  (40120300000000000030QE)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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  (40120300000000000036QS)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Certification as follows: G3M 18 03 12163 068; NB 0123
seca 232 n / 2321717008 seca 232 / 2321817008 seca 233 / 2331714004 seca 233 / 2331814004  (40120300000000000043QP)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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
		<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	NB 0123
seca 234 / 2341717009 seca 234 / 2341817009  (40120300000000000056QY)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Certification as follows: G3M 18 03 12163 068; NB 0123
seca 264 / 2641900099 seca 264 / 2641900009 seca 274 / 2741900099 seca 274 / 2741900009  (40120300000000000041QK)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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  (40120300000000000057R2)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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  (40120300000000000058R4)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Certification as follows: G3M 18 03 12163 068; NB 0123
seca 310 / 3101017654  (40120300000000000035QQ)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Certification as follows: G3M 18 03 12163 068; NB 0123
seca 334 / 3341021008 seca 334 / 3341321008 seca 334 / 3341321619  (40120300000000000047QX)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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  <b>(401203000000000000042QM)</b>		<input type="checkbox"/> 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  <b>(401203000000000000046QV)</b>	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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  <b>(401203000000000000037QU)</b>	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Certification as follows: G3M 18 03 12163 068; NB 0123
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seca 703 / 7031321007 seca 704 / 7047021008 seca 704 / 7047021098 seca 704 / 7047021228	<input type="checkbox"/> N/A  or	<input checked="" type="checkbox"/> N/A  or	<input type="checkbox"/> 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  <b>(40120300000000000038QW)</b>	<input checked="" type="checkbox"/> Class I devices with a measuring function	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input checked="" type="checkbox"/> Certification as follows: G3M 18 03 12163 068; NB 0123
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seca 755 / 7551021004 seca 755 / 7551321004 seca 755 / 7551421004 seca 756 / 7567021004 seca 786 / 7862021004  <b>(401203000000000000053QS)</b>	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> 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  <b>(401203000000000000063QV)</b>	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> 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  <b>(401203000000000000048QZ)</b>	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> 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	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> 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
<b>(40120300000000000054QU)</b> 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	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Certification as follows: G3M 18 03 12163 068; NB 0123
<b>(40120300000000000052QQ)</b> seca 769 s / 7691321998 seca 799 s / 7997021304  <b>(40120300000000000062QT)</b>	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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 <b>(40120300000000000059R6)</b>	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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  (40120300000000000029QV)			
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  (40120300000000000049R3)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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  (40120300000000000040QH)	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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.	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Certification as follows: Certificate #: Certificate #:  or  <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives  or  <input type="checkbox"/> 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