

To whom it may concern

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Our reference: QS-7092, PP-13195, PP-13226, PP-13261,
PP-13211, PP-13185, PP-13188, PP-13222,
PP-13190, PP-13191, PP-13214

Notified Body Confirmation Letter
Certification No: 7092GB454231228

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

To whom it may concern,

This letter confirms that DNV Medcert GmbH, a Notified Body (NB), designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0482 on Nando¹, 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.

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany
SRN²: DE-MF-000010002

The devices covered by the formal application and the written agreement mentioned above are identified in the tables (in the appendix of this letter). Table 1 identifies the devices for which an MDR application has been received, a written agreement concluded and for which the NB 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 NB 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 2023 for the relevant devices.

¹ Nando (New Approach Notified and Designated Organisations) Information System, <https://ec.europa.eu/growth/tools-databases/nando/>.

² Single registration number (SRN) according to Article 31 (2) of MDR.

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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 devices, 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)

For DNV MEDCERT GmbH



Birgit Dose
Customer Service

Appendix (see following pages):

- Table 1 and Table 2
- Revision history



Appendix

Table 1: Devices covered by this letter and for which the NB is also 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
4048844MUT2MINS15TINSK 4048844MUTCOLOVALTCPPN 4048844MUTCOLROUNDTC6P 4048844MUTCOLTIBIALTCP5G 4048844MUTCONPUNCQG 4048844MUTENDPUNCCMP 4048844MUTEXTPUNCX9 4048844MUTFEMSSUNCH6 4048844MUTFEMSTHACDEE 4048844MUTFEMSTHACLEW 4048844MUTFEMSTTINCDRA 4048844MUTFEMSTUNCCDQZ 4048844MUTFEMSTUNCCLRH 4048844MUTICMGENUXMKUNCUH 4048844MUTICMGENUXUNCSQ 4048844MUTICMKRIUNCFR 4048844MUTLUMICCUPHATD 4048844MUTLUMICCUPUNC7X 4048844MUTLUMICFBOLTRN 4048844MUTLUMICSCREWUNCCG 4048844MUTLUMICSSUNCZW 4048844MUTLUMICSTHACL8R 4048844MUTLUMICSTUNCCDUJ 4048844MUTPRFEMREVUNC8W 4048844MUTPRFEMUNCM2 4048844MUTPTXPUNC28 4048844MUTPTFEMSTHACL9M 4048844MUTPTREDUNCQZ 4048844MUTPTSCREWUNC7F 4048844MUTREDUNC2N 4048844MUTRSCODEUNCNC 4048844MUTRSCUPFBOLT3G 4048844MUTRSCUPLUNCCLJQ 4048844MUTRSCUPRUNCCLM6 4048844MUTRSEXTPHAX 4048844MUTRSEXTPUNC33 4048844MUTRSMCHA5X 4048844MUTRSMCUNCWV 4048844MUTRSPCUNCXW 4048844MUTRSSCCODEUNC9B 4048844MUTRSSCREWUNC8J 4048844MUTRSSSUNC4J 4048844MUTRSSTHACLUH 4048844MUTRSSTTINCD5A 4048844MUTRSSTUNCCD4Z 4048844MUTRSSTUNCCL5H 4048844MUTRSSTXSHACLHX 4048844MUTSCONPUNCN9 4048844MUTSCREWUNCMW 4048844MUTSTMCTINCDUE 4048844MUTSTMUNCDDU5 4048844MUTSTMSTINCD2Z 4048844MUTSTMSUNCCD2Q 4048844MUTTPPRFEMREVUNCSX 4048844MUTXLPEINS15N05M 4048844MUTXLPEINS15O45Y 4048844MUTCONPSJQ 4048844MUTHMRSADFSJA	Class III	N/A	Certificate 13195DE411200427 NB 0482 Certificate 13195GB411200427 NB 0482

<p>4048844MUTHMRSADMSJX 4048844MUTREDSAS 4048844MUTPRFEMS56 4048844MUTPRFEMREVSP2 4048844MUTEXTPSNB 4048844MUTENDPSHM 4048844MUTRSPCSPU 4048844MUTICMKRISME 4048844MUTICMGENUXSCP 4048844MUTICMGENUXMKSS7 4048844MUTRSCODESTK 4048844MUTLUMICCUPS NH</p>			
<p>4048844MUTCONPTIBUNCRH 4048844MUTCOTINBNPG 4048844MUTCOUNCJM 4048844MUTPEMETTIBH5 4048844MUTPEMETTIBMKQC 4048844MUTFEMDHTIN7G 4048844MUTFEMDHDUNC7E 4048844MUTFEMDMOMTINFR 4048844MUTFEMDMOMUNCFP 4048844MUTFEMDTINK4 4048844MUTFEMDUNCK2 4048844MUTFEMGMKHDHTINCDFT 4048844MUTFEMGMKHDHTINCLGB 4048844MUTFEMGMKHDUNCCDFJ 4048844MUTFEMGMKHDUNCCLG2 4048844MUTFEMGMKMUNCCDKT 4048844MUTFEMGMKMUNCCD3H 4048844MUTFEMGMKTINCDNY 4048844MUTFEMGMKTINCLPG 4048844MUTFEMGMKUNCCDNP 4048844MUTFEMGMKUNCCLP7 4048844MUTFEMGTINCDBS 4048844MUTFEMGTINCLCA 4048844MUTFEMGUNCCDBH 4048844MUTFEMGUNCCLBZ 4048844MUTFEMKRIHDTINQ4 4048844MUTFEMKRIHDUNCQ2 4048844MUTFEMKRIMOMTITU 4048844MUTFEMKRIMOMUNU9 4048844MUTFEMKRITINEU 4048844MUTFEMKRIUNCES 4048844MUTGENMKOFADUNC2P 4048844MUTHDCOCOMTINCP 4048844MUTHDCOCOMUNCCM 4048844MUTHDCOMOMCPEGL6 4048844MUTHDCOMOMTINBN4G 4048844MUTHDCOMOMUNCGP 4048844MUTPATPESTDUDUF 4048844MUTPEEKOPLOCKPWQ 4048844MUTPEFBSTDMT 4048844MUTPEGENMKFBSTD5C 4048844MUTPEGENMKFBXLE5F 4048844MUTPEGENMKMBSTD7R 4048844MUTPEGENMKMBXLE7U 4048844MUTPEGTIBGMKTIN9T 4048844MUTPEGTIBGMKUNC9R 4048844MUTPEGTIBMOMTINDD 4048844MUTPEGTIBMOMUNCDB 4048844MUTPLUGTIB2MOM6A 4048844MUTPLUGTIBMOM23 4048844MUTSCRCOUNT2 4048844MUTSCRCOUPT6 4048844MUTSCRKRI4M 4048844MUTSCRSPAFEMPU 4048844MUTSCRSPAMKNG 4048844MUTSCRSPATIBCXW</p>	<p>Class III</p>	<p>N/A</p>	<p>Certificate 13226GB411200831 NB 0482 Certificate 13226DE411200831 NB 0482</p>

<p>4048844MUTSCRSPATIBRQ 4048844MUTSCRTIBMODPJ 4048844MUTSCRTIBMOMQ4 4048844MUTSFEMUNCRK 4048844MUTSLFEMUNCKM 4048844MUTSMKFEMDUNCT7 4048844MUTSMKFEMPUNCVT 4048844MUTSMKTIBBIUNC7A 4048844MUTSMKTIBUNCSU 4048844MUTSTGENMKEXUNCTH 4048844MUTSTGENMKHACL89 4048844MUTSTGENMKTINCDTB 4048844MUTSTGENMKUNCCDT2 4048844MUTSTGENMKUNCCLTJ 4048844MUTSTGENTINCD2H 4048844MUTSTGENUNCCD28 4048844MUTSTGENUNCC2Q 4048844MUTSTIBUNCW8 4048844MUTSTTIBCPTICDEM 4048844MUTSTTIBHACDS5 4048844MUTSTTIBHACL5M 4048844MUTSTTIBMTIBCDGK 4048844MUTSTTIBMUNCCDJ6 4048844MUTSTTIBMUNCLJN 4048844MUTSTTIBPTHACLHW 4048844MUTSTTIBTINCD7G 4048844MUTSTTIBUNCCD77 4048844MUTSTTIBUNCC7P 4048844MUTTIBBMKUNCCLVH 4048844MUTTIBBTINCLGU 4048844MUTTIBGMKUNCDYG 4048844MUTTIBGMKTIBCDWD 4048844MUTTIBGMKTIBCLWV 4048844MUTTIBGMKUNCCDXY 4048844MUTTIBGMKUNCCLYG 4048844MUTTIBMKPRTINW7 4048844MUTTIBMOMTINCD5S 4048844MUTTIBMOMTINCL6A 4048844MUTTIBMOMUNCCD5H 4048844MUTTIBMOMUNCC5Z 4048844MUTTIBMPROUNCY7 4048844MUTPEEKOPLOCKP7 4048844MUTCONPTIBSILRA 4048844MUTSFEMSILRC 4048844MUTSLFEMSILKE 4048844MUTSTIBSILVZ 4048844MUTFEMDMOMSILFG 4048844MUTFEMDMOMTSBU 4048844MUTFEMDSILJT 4048844MUTFEMKRIMOMTSUG 4048844MUTSMKFEMDSILSY 4048844MUTSMKFEMPSILVL 4048844MUTSMKTIBBISIL73 4048844MUTSMKTIBSILSM 4048844MUTTIBMKPRVILVW 4048844MUTTIBMOMSILCD55 4048844MUTTIBMPROSILXY 4048844MUTHDCOPEGA8F 4048844MUTHDCOPEGB8H</p>			
<p>4048844MUTHUAXLD2UNCNM 4048844MUTHUAXLDTINBN65 4048844MUTHUAXLDUNCMG 4048844MUTHUCAPITINFQ 4048844MUTHUCAPTINFZ 4048844MUTHUCOLFTCPJX</p>	<p>Class III</p>	<p>N/A</p>	<p>Certificate 13266DE411180608 NB 0482 Certificate 13266GB411180608</p>

<p>4048844MUTHUCOLTCPKH 4048844MUTHUONPUNCN7 4048844MUTHUDH230UNCXQ 4048844MUTHUDH250UNCYE 4048844MUTHUDH30UNC46 4048844MUTHUDH50TINBNA 4048844MUTHUDH50UNC4U 4048844MUTHUENDPUNCKE 4048844MTHUEXTPUNCUY 4048844MTHUGLENUNCKK 4048844MTHUGLRHACLK5 4048844MTHUGLUNCCDMA 4048844MTHUHEADUNCDP 4048844MTHUHSSUNCQT 4048844MTHUHSUNCU6 4048844MTHULSDUNCP6 4048844MTHUPEFCSTDKR 4048844MTHUPESCSTDQ8 4048844MTHUREDUNCLS 4048844MTHUSCONPUNCZ6 4048844MTHUSDSW5UNCYQ 4048844MTHUSSD30UNCMG 4048844MTHUSTAMTINCDDY 4048844MTHUSTAMUNCCDDP 4048844MTHUSTAMUNCCLE7 4048844MTHUSTHACDP5 4048844MTHUSTHACLPM 4048844MTHUSTOP2UNC4M 4048844MTHUSTOPUNCZ3 4048844MTHUSTTINCX7 4048844MTHUSTUNCCDWW 4048844MTHUSTUNCCLXE 4048844MTHUUA2CPHACLME 4048844MTHUUACPHACLPR 4048844MTHUUATINBNCL9H 4048844MTHUUC2UNCCDM6 4048844MTHUUCITINC7X 4048844MTHUUCTINBNCA7 4048844MTHUUCUNCCDR3 4048844MTHUULNA2TINTY 4048844MTHUULNA2UNCTW 4048844MTHUULNAUNCT9 4048844MTHUHEADSN2 4048844MTHUEXTPSV9 4048844MTHUONPSRN 4048844MTHUENDPSQK 4048844MTHUREDS4Q 4048844MTHUDH50SHT 4048844MTHUULNASVS</p>			NB 0482
<p>4048844AGILOCAPITIN9J 4048844AGILOCAPTINEV 4048844AGILOCTACAPTINAZ 4048844AGILOEXTPRUNCU6 4048844AGILOEXTPUNCNS 4048844AGILOGLAHACL74 4048844AGILOGLBAUNCCLBX 4048844AGILOGLBRUNCCLJU 4048844AGILOGLPEICLCU 4048844AGILOGLPEIXLECLVX 4048844AGIOMETOAWR 4048844AGIOMETPRXW 4048844AGIOMETTRRNA 4048844AGIOMETTRYA 4048844AGILOMICLCE 4048844AGILONGLRHACLG5 4048844AGILOPEGLENHX</p>	Class III	N/A	Certificate 13261GB411200529 NB 0482 Certificate 13261DE411200529 NB 0482

<p>4048844AGILOPEGLENXLEKK 4048844AGILOPEGLXLECDMS 4048844AGILORCAPITINF4 4048844AGILOSRTIN3Z 4048844AGILOSSUNC46 4048844AGILOSTING5 4048844AGILOSTRTINCDWV 4048844AGILOSTRUNCDDWL 4048844AGILOSTRUNCCLX4 4048844AGILOSTTINCDQZ 4048844AGILOSTUNCCDQQ 4048844AGILOSTUNCCLR8</p>			
<p>4048844ECO2MCUPCDTINWE 4048844ECO2MCUPCDUNCWC 4048844ECO2MCUPCLCPHAY2 4048844ECO2MCUPCLSPCPHAQN 4048844ECO2MHEADPEZ6 4048844ECO2MHEADXLESU</p>	Class III	N/A	<p>Certificate 13211DE411180302 NB 0482 Certificate 13211GB411180302 NB 0482</p>
<p>4048844BICANRSTUNCCDHD 4048844BICANSTUNCCDDV</p>	Class III	N/A	<p>Certificate 13185DE411180528 NB 0482 Certificate 13185GB411180528 NB 0482</p>
<p>4048844ECOSTCPHACLSDQS 4048844ECOSTCPHACLAPX 4048844ECOSTCPHACLSD3K 4048844ECOSTCPHACLLA2Q 4048844ECOSTCPCLSDTM 4048844ECOSTCPCLLASS 4048844ECOSTUNCTICDSDCN 4048844ECOSTUNCCDSDWL 4048844ECOSTTINCDSXT 4048844ECOSTUNCCDLAVR 4048844ECOSTTINCDLAWY 4048844ECOSTUNCHPCSDA7 4048844ECOSTUNCHPCDLA9C 4048844ECOSTCVCPCLSDX4 4048844ECOSTCVCPHACLSDCN 4048844ECOSTCVUNCCDSD9J 4048844ECOSTCVUNCHPCDSDB3 4048844ECOST133CPCLSDQN 4048844ECOST133CPCLLAPT 4048844ECOST133CPHACLSDY9 4048844ECOST133CPHACLLAXE 4048844ECOST133UNCCDSY9 4048844ECOST133UNCCDLAXE 4048844ECOST133UNCHPCDSBB 4048844ECOST133UNCHPCDLAV 4048844ECOSTSSTCPCLSDKY 4048844ECOSTSSTCPCLLAK5 4048844ECOSTSSTCPHACLSDKL 4048844ECOSTSSTCPHACLLAJR</p>	Class III	N/A	<p>Certificate 13188DE411190409 NB 0482 Certificate 13188GB411190409 NB 0482</p>
<p>4048844ICHEADCOCRUNCW3 4048844ICHEADCOCRTINW5 4048844ICHEADTITANTIN7F 4048844ICBIPOCOCRMOPEGZ</p>	Class III	N/A	<p>Certificate 13190DE411210112A NB 0482 Certificate 13190GB411210112A NB 0482</p>
<p>4048844CUPINS0PENN 4048844CUPINS10PE5N 4048844CUPINS0XLEPEY6 4048844CUPINS10XLEPEPE 4048844CUPINS0XLPEZT 4048844CUPINS10XLPENV</p>	Class III	N/A	<p>Certificate 13191DE411210118A NB 0482 Certificate 13191GB411210118A NB 0482</p>

<p>4048844ECOFITINSTINMM 4048844ECOFITINSUNCMK 4048844CERACODINS1057 4048844CERACORINS10AV 4048844ECOCUCPCLDE 4048844ECOCUCPHACLH2 4048844ECOCUNHCPCLKZ 4048844ECOCUNHCPHACLES 4048844ECOEPNCHUNCCLFQ 4048844ECOEPUNCLZD 4048844ECOEPNCHNHUNCCLVL 4048844ECOEPNHUNCCLKF 4048844ECOEPNCHMHUNCCLV3 4048844ECOEPMHUNCCLJW 4048844ECOEPNCHTGPCLEZ 4048844ECOEPTCPCLYN 4048844ECOEPNCHMHTCPCLUC 4048844ECOEPMHTCPCLJ7 4048844CHOLECOVERM10X1RQ 4048844ECOSCUNCCL3M 4048844CENTRAPLUGM16X18A 4048844MUELPECUPCD5Q 4048844MUELXLECUPCD9J 4048844MUELPECUPSNAPCDWA 4048844MUELPECUPDYSCDJC</p>	<p>Class III</p>	<p>N/A</p>	<p>Certificate 13214DE411190903 NB 0482 Certificate 13214GB411190903 NB 0482</p>
<p>4048844ICHEADBIOLOXDVY 4048844ICHEADBIOLOXDRX2 4048844TAICHEADBIOLOXDRTS 4048844CUPINSBIOLOXDELTG8</p>	<p>Class III</p>	<p>N/A</p>	<p>Certificate 13222DE411210212A NB 0482 Certificate 13222GB411210212A NB 0482</p>
<p>4048844ACSFEMTINCDGH 4048844ACSFEMUNCCDG8 4048844ACSFEMTINTCPCLUU 4048844ACSFEMTINCLGZ 4048844ACSFEMUNCCLGQ 4048844ACSFEMPSTINCDJ2 4048844ACSFEMPSUNCCDHR 4048844ACSFEMPSTINCLJJ 4048844ACSFEMSCINCLDD5 4048844ACSFEMSCUNCCDCU 4048844ACSFEMSCINCLDM 4048844ACSFEMLSTINCLDFW 4048844ACSTIBMBTINCDJK 4048844ACSTIBMBUNCCDJA 48844ACSTIBMBTINTCPCLJX 4048844ACSTIBMBTINCLK3 4048844ACSTIBMBUNCCLJS 4048844ACSTIBMBBTINCDHV 48844ACSTIBMBBUNCCDHL 4048844ACSTIBMBBTINCLJD 4048844ACSTIBMBSC2TINCD4P 4048844ACSTIBMBSC2TINCL57 4048844ACSTIBMBSC2TINCL57 4048844ACSTIBMBSC2TINCLZ3 4048844ACSTIBMBSCUNCCLYS 4048844ACSTIBFBTINCDEU 4048844ACSTIBFB+TINCD4S 4048844ACSTIBFBTINCLFC 4048844ACSTIBFB+TINCL5A 4048844ACSTIBFBUNCCDEK 4048844ACSTIBFB+UNCCD4H 4048844ACSTIBFBUNCCLF3</p>	<p>Class III</p>	<p>N/A</p>	<p>Certificate 13222DE411210212A NB 0482 Certificate 13222GB411210212A NB 0482</p>

<p>4048844ACSTIBFB+UNCCL4Z 4048844ACSPLUGCONEFBPQ 4048844ACSPLUGLOCKFBCLAJ 4048844ACSPLUGLOCKFBCDA2 4048844ACSSPMBSC TIBR2 4048844ACSSCSPSCHE 4048844ACSSPFBTIBMP5 4048844ACSSPFBTIBLP3 4048844ACSSCSPFBTIBMH 4048844ACSEXTSTTINZ2 4048844ACSEXTSTUNCYY 4048844ACSEXTSTMTTIN76 4048844ACSEXTSTMTUNC74 4048844ACSSTUNC85 4048844ACSSTHACLHK 4048844ACSOFAADBAD 4048844ACSOFAADB MKCD 4048844ACSDTAPTG 4048844ACSDTAPMKD6 4048844ACSPEMBSTD XQ 4048844ACSPEMBNCSTDFM 4048844ACSPEMBDDSTDCE 4048844ACSPEMBPSHSTD L9 4048844ACSPEMBSCHSTDFY 4048844ACSPFBHSTDFK 4048844ACSPFB+HSTDZ8 4048844ACFBPESTDSV 4048844ACFB+PESTDZJ 4048844ACSPFBPSHSTDG4 4048844ACSPFB+PSHSTD2J 4048844ACSPFBUSTDJE 4048844ACSPFB+USTD46 4048844ACSPFBSCSTDDM 4048844ACSPFB+SCSTDYA 4048844ACSPFBXLEVE 4048844ACSPFB+XLE9J 4048844ACSPFBHXLEFN 4048844ACSPFB+HXLEZB 4048844ACSPFBPSHXLEG7 4048844ACSPFB+PSHXLE2M 4048844ACSPFBUXLEJH 4048844ACSPFB+UXLE49 4048844ACSPFBSCXLEDQ 4048844ACSPFB+SCXLEYD 4048844ACSPAROTINCDN7 4048844ACSPAROTINPCCLW4 4048844ACSPAROTINCLNP 4048844ACSPAPESTDXS 4048844ACSPASTDCDY6 4048844ACSPAXLECDYA 4048844ACSPAANTSTDCDGX 4048844ACSPAANTXLECDH3 4048844ACSEPMETTIBFBHV 4048844ACSEPMETFEMGMKL2 4048844ACSEPMETFEMSCF7 4048844ACSSCREPMETTIBUR 4048844ACSEPMETTIB5H5 4048844ACSEPMETTIB10EX</p>			
<p>4048844ANBSCHLNRESJY 4048844TARICTIBCLAN 4048844TARICTIBCLINWU 4048844TARICTALCLAG 4048844TARICTALCLINWN 4048844TARICPEINLAJ</p>	<p>Class III</p>	<p>N/A</p>	<p>Certificate 7092DE410201201A NB 0482 Certificate 7092GB410201201A NB 0482</p>

4048844ICARahr5 4048844ICARASCSH 4048844ICARASCLY7 4048844AAATALCOMPKF 4048844AAATIBCOMPK9 4048844AAAPEINLS2			
4048844MUTARTSTDVENUNCTN 4048844MUTARTSTDORUNCQN 4048844MUTARTSTDAXUNC9U 4048844MUTARTSCSTDUNC93 4048844MUTARTTIBPLAUNCHW 4048844MUTARTTIBPLATINHY 4048844MUTARTRSFEMUNC8H 4048844MUTARTRSTIBUNCD6 4048844MUTARTSCUNCLF 4048844MUTDUC4K 4048844MUTDTINA8 4048844MUTDCP3P 4048844EDIAIMPRB 4048844MUTHUDUCKN	Class IIb implantable non- WET device	N/A	Certificate 7092DE410201201A NB 0482 Certificate 7092GB410201201A NB 0482

Table 2: Devices covered by this letter and for which the NB 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
None	None	None	None

Confirmation Letter Revision History:

Date	NB internal reference traceable to each version of the letter	Action
2023-06-29	N/A	Initial issue
2023-07-13	N/A	Correction Basic UDI-DI
2023-07-17	N/A	Correction Basic UDI-DI
2023-08-07	7092GB454230807	Insert of Certificate Number
2023-12-28	7092GB454231228	Addition of devices/removal of already MDR certified REFs