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Swiss Medical Instruments AG
Mr. André Gasser
Roosstrasse 10A
8832 Wollerau
Switzerland

22 May 2024

Notified Body Confirmation Letter

Client number: 1707

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, QMD Services GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2962 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:

Swiss Medical Instruments AG
Roosstrasse 10A
8832 Wollerau
Switzerland
SRN Number (if available): CH-MF-000041217

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, 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, with-

out having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 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,

ppa Ingrid Blaimauer

Head of operations

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 preliminarily 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
Device 1 **300.001 Hip-Screw 6mm**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 2 **300.010 Hip-Screw 6.5mm**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 3 **300.005 Capsa-Knife**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 4 **300.033 Drill Ø 4.7mm**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 5 **300.156 Drill Ø 4.9mm**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 6 **201.006 Oval Burr Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 7 **202.006 Oval Burr Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 8 **203.006 Oval Burr Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 9 **201.004 Oval Burr Ø 4.2 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 10 **202.004 Oval Burr Ø 4.2 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 11 **203.004 Oval Burr Ø 4.2 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 12 **201.007 Oval Burr Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 13 **202.007 Oval Burr Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 14 **203.007 Oval Burr Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 15	Class IIa	N/A	Reg. no. 42362

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and preliminarily 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
201.005 Oval Burr Ø 5.5 for frontal use			CE 1250
Device 16 **202.005 Oval Burr Ø 5.5 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 17 **203.005 Oval Burr Ø 5.5 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 18 **201.008 Oval Burr Ø 6.5 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 19 **202.008 Oval Burr Ø 6.5 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 20 **203.008 Oval Burr Ø 6.5 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 21 **201.009 Round Burr Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 22 **202.009 Round Burr Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 23 **203.009 Round Burr Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 24 **201.012 Round Burr Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 25 **202.012 Round Burr Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 26 **203.012 Round Burr Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 27 **201.011 Round Burr Ø 5.5 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 28 **202.011 Round Burr Ø 5.5 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 29 **203.011 Round Burr Ø 5.5 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and preliminarily 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
Device 30 **201.013 Tapered Burr Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 31 **202.013 Tapered Burr Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 32 **203.013 Tapered Burr Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 33 **201.014 Aggressive Full-Radius Ø 4.2 Curved**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 34 **202.014 Aggressive Full-Radius Ø 4.2 Curved**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 35 **203.014 Aggressive Full-Radius Ø 4.2 Curved**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 36 **201.015 Aggressive Full-Radius Resector Ø 3.4**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 37 **202.015 Aggressive Full-Radius Resector Ø 3.4**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 38 **203.015 Aggressive Full-Radius Resector Ø 3.4**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 39 **201.016 Aggressive Full-Radius Resector Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 40 **202.016 Aggressive Full-Radius Resector Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 41 **203.016 Aggressive Full-Radius Resector Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 42 **201.017 Aggressive Full-Radius Resector Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 43 **202.017 Aggressive Full-Radius Resector Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and preliminarily 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
Device 44 **203.017 Aggressive Full-Radius Resector Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 45 **201.018 Cutter Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 46 **202.018 Cutter Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 47 **203.018 Cutter Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 48 **201.001 Cutting-Blade Ø 3.4**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 49 **202.001 Cutting-Blade Ø 3.4**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 50 **203.001 Cutting-Blade Ø 3.4**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 51 **201.019 Cutting-Blade Ø 3.4 Bendable**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 52 **202.019 Cutting-Blade Ø 3.4 Bendable**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 53 **203.019 Cutting-Blade Ø 3.4 Bendable**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 54 **201.002 Cutting-Blade Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 55 **202.002 Cutting-Blade Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 56 **203.002 Cutting-Blade Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 57 **201.020 Cutting-Blade Ø 4.2 Bendable**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 58	Class IIa	N/A	Reg. no. 42362

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and preliminarily 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
202.020 Cutting-Blade Ø 4.2 Bendable			CE 1250
Device 59 **203.020 Cutting-Blade Ø 4.2 Bendable**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 60 **201.010 Cutting-Blade Ø 4.2 Curved**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 61 **202.010 Cutting-Blade Ø 4.2 Curved**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 62 **203.010 Cutting-Blade Ø 4.2 Curved**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 63 **201.003 Cutting-Blade Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 64 **202.003 Cutting-Blade Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 65 **203.003 Cutting-Blade Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 66 **201.021 Double Aggressive Full-Radius Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 67 **202.021 Double Aggressive Full-Radius Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 68 **203.021 Double Aggressive Full-Radius Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 69 **201.022 Double Aggressive Full-Radius Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 70 **202.022 Double Aggressive Full-Radius Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and preliminarily 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
Device 71 **203.022 Double Aggressive Full-Radius Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 72 **201.023 End Cutter Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 73 **202.023 End Cutter Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 74 **203.023 End Cutter Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 75 **201.024 End Cutter Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 76 **202.024 End Cutter Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 77 **203.024 End Cutter Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 78 **201.025 Full Radius Resector Ø 3.4**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 79 **202.025 Full Radius Resector Ø 3.4**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 80 **203.025 Full Radius Resector Ø 3.4**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 81 201.026 Full Radius Resector Ø 4.2	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 82 **202.026 Full Radius Resector Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 83 **203.026 Full Radius Resector Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 84 **201.027 Full Radius Resector Ø 4.2 Curved**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 85	Class IIa	N/A	Reg. no. 42362

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and preliminarily 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
202.027 Full Radius Resector Ø 4.2 Curved			CE 1250
Device 86 **203.027 Full Radius Resector Ø 4.2 Curved**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 87 **201.028 Full Radius Resector Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 88 **202.028 Full Radius Resector Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 89 **203.028 Full Radius Resector Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 90 **201.029 Meniscus Cutter Ø 3.4**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 91 **202.029 Meniscus Cutter Ø 3.4**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 92 **203.029 Meniscus Cutter Ø 3.4**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 93 **201.030 Meniscus Cutter Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 94 **202.030 Meniscus Cutter Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 95 **203.030 Meniscus Cutter Ø 4.2**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 96 **201.031 Meniscus Cutter Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 97 **202.031 Meniscus Cutter Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 98 **203.031 Meniscus Cutter Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 99	Class IIa	N/A	Reg. no. 42362

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and preliminarily 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
204.001 Cutting-Blade Ø 3.5			CE 1250
Device 100 **204.002 Cutting-Blade Ø 4.3**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 101 **204.003 Cutting-Blade Ø 5.6**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 102 **204.004 Oval Burr Ø 4.2 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 103 **204.005 Oval Burr Ø 5.5 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 104 **204.006 Oval Burr Ø 4.3**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 105 **204.007 Oval Burr Ø 5.6**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 106 **204.008 Oval Burr Ø 6.5 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 107 **204.009 Round Burr Ø 4.3**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 108 **204.010 Cutting-Blade Ø 4.2 Curved**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 109 **204.011 Round Burr Ø 5.5 for frontal use**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 110 **204.012 Rund Burr Ø 5.6**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 111 **204.013 Tapered Burr Ø 5.6**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 112 **204.014 Aggressive Full-Radius Ø 4.2 Curved**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 113 **204.015 Aggressive Full-Radius Resector Ø 3.5**	Class IIa	N/A	Reg. no. 42362 CE 1250

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and preliminarily 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
Device 114 **204.016 Aggressive Full-Radius Resector Ø 4.3**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 115 **204.017 Aggressive Full-Radius Resector Ø 5.6**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 116 **204.018 Cutter Ø 4.3**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 117 **204.019 Cutting-Blade Ø 3.4 Bedable**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 118 **204.020 Cutting-Blade Ø 4.2 Bendable**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 119 **204.021 Double Aggressive Full-Radius Ø 4.3**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 120 **204.022 Double Aggressive Full-Radius Ø 5.6**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 121 **204.023 End Cutter Ø 4.3**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 122 **204.024 End Cutter Ø 5.6**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 123 **204.025 Full Radius Resector Ø 3.5**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 124 **204.026 Full Radius Resector Ø 4.3**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 125 204.027 Full Radius Resector Ø 4.2 Curved	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 126 **204.028 Full Radius Resector Ø 5.6**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 127 **204.029 Meniscus Cutter Ø 3.5**	Class IIa	N/A	Reg. no. 42362 CE 1250

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and preliminarily 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
Device 128 **204.030 Meniscus Cutter Ø 4.3**	Class IIa	N/A	Reg. no. 42362 CE 1250
Device 129 **204.031 Meniscus Cutter Ø 5.5**	Class IIa	N/A	Reg. no. 42362 CE 1250

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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 preliminarily 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
NA	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
22 May 2024	1707	Initial issue