



EC DECLARATION OF CONFORMITY

Manufacturer Name: AISER SA

Manufacturer Address: 14 Rue du Rhone, 1204 Geneve, Switzerland

Authorized Representative: AISER ITALIA SRL Viale Lombardia 217, Monza, 20900 Italy
ref. to Annex 1 – Product codes

Devices Description: ref. to Annex 1 – Product codes

Product code: Class IIb according to Annex IX, Rule 8 and Rule 17 of the
Directive 93/42/EEC

Classification: CE 0068

Notified Body: Annex II of Directive 93/42/EEC

Conformity Assessment procedure: CE 0068/QCO-DM/348-2021

Certificate number: SQ/110-2021

We declare under our sole responsibility that the above mentioned medical devices comply with all provisions of Council Directive 93/42/EEC and subsequent amendments and Regulation 722/2012 with respect to active implantable medical devices and medical devices manufactured utilizing tissues of animal origin.

Geneve (CH), 19.03.2024

Antonello Malacrinò
Chief Executive Officer **AISER SA**

A handwritten signature in blue ink, appearing to be the name Antonello Malacrinò, is written over a faint circular stamp.



ANNEX 1 - PRODUCT CODES

PRODUCT CODE	ITEM DESCRIPTION
TY35V06	TYTAN IMPLANT SYSTEM H 06 - 3.5 VIOLET
TY35V07	TYTAN IMPLANT SYSTEM H 07 - 3.5 VIOLET
TY35V08	TYTAN IMPLANT SYSTEM H 08 - 3.5 VIOLET
TY35V10	TYTAN IMPLANT SYSTEM H 10 - 3.5 VIOLET
TY35V11	TYTAN IMPLANT SYSTEM H 11 - 3.5 VIOLET
TY35V13	TYTAN IMPLANT SYSTEM H 13 - 3.5 VIOLET
TY35V15	TYTAN IMPLANT SYSTEM H 15 - 3.5 VIOLET
TY35V18	TYTAN IMPLANT SYSTEM H 18 - 3.5 VIOLET
TY35V20	TYTAN IMPLANT SYSTEM H 20 - 3.5 VIOLET
TY35V22	TYTAN IMPLANT SYSTEM H 22 - 3.5 VIOLET
TY43G06	TYTAN IMPLANT SYSTEM H 06 - 4,3 GREY
TY43G07	TYTAN IMPLANT SYSTEM H 07 - 4,3 GREY
TY43G08	TYTAN IMPLANT SYSTEM H 08 - 4,3 GREY
TY43G10	TYTAN IMPLANT SYSTEM H 10 - 4,3 GREY
TY43G11	TYTAN IMPLANT SYSTEM H 11 - 4,3 GREY
TY43G13	TYTAN IMPLANT SYSTEM H 13 - 4,3 GREY
TY43G15	TYTAN IMPLANT SYSTEM H 15 - 4,3 GREY
TY43G18	TYTAN IMPLANT SYSTEM H 18 - 4,3 GREY
TY43G20	TYTAN IMPLANT SYSTEM H 20 - 4,3 GREY
TY43G22	TYTAN IMPLANT SYSTEM H 22 - 4,3 GREY
TY50B06	TYTAN IMPLANT SYSTEM H 06 - 5,0 BLUE
TY50B07	TYTAN IMPLANT SYSTEM H 07 - 5,0 BLUE
TY50B08	TYTAN IMPLANT SYSTEM H 08 - 5,0 BLUE
TY50B10	TYTAN IMPLANT SYSTEM H 10 - 5,0 BLUE
TY50B11	TYTAN IMPLANT SYSTEM H 11 - 5,0 BLUE
TY50B13	TYTAN IMPLANT SYSTEM H 13 - 5,0 BLUE
TY50B15	TYTAN IMPLANT SYSTEM H 15 - 5,0 BLUE
TY55Y06	TYTAN IMPLANT SYSTEM H 06 - 5,5 YELLOW
TY55Y07	TYTAN IMPLANT SYSTEM H 07 - 5,5 YELLOW
TY55Y08	TYTAN IMPLANT SYSTEM H 08 - 5,5 YELLOW
TY55Y10	TYTAN IMPLANT SYSTEM H 10 - 5,5 YELLOW
TY55Y11	TYTAN IMPLANT SYSTEM H 11 - 5,5 YELLOW
TY55Y13	TYTAN IMPLANT SYSTEM H 13 - 5,5 YELLOW
TH35V06	THEMYS IMPLANT SYSTEM H 06 - 3,5 VIOLET
TH35V07	THEMYS IMPLANT SYSTEM H 07 - 3,5 VIOLET
TH35V08	THEMYS IMPLANT SYSTEM H 08 - 3,5 VIOLET
TH35V10	THEMYS IMPLANT SYSTEM H 10 - 3,5 VIOLET
TH35V11	THEMYS IMPLANT SYSTEM H 11 - 3,5 VIOLET
TH35V13	THEMYS IMPLANT SYSTEM H 13 - 3,5 VIOLET
TH35V15	THEMYS IMPLANT SYSTEM H 15 - 3,5 VIOLET
TH35V18	THEMYS IMPLANT SYSTEM H 18 - 3,5 VIOLET
TH35V20	THEMYS IMPLANT SYSTEM H 20 - 3,5 VIOLET
TH35V22	THEMYS IMPLANT SYSTEM H 22 - 3,5 VIOLET
TH43G06	THEMYS IMPLANT SYSTEM H 06 - 4,3 GREY
TH43G07	THEMYS IMPLANT SYSTEM H 07 - 4,3 GREY
TH43G08	THEMYS IMPLANT SYSTEM H 08 - 4,3 GREY
TH43G10	THEMYS IMPLANT SYSTEM H 10 - 4,3 GREY
TH43G11	THEMYS IMPLANT SYSTEM H 11 - 4,3 GREY
TH43G13	THEMYS IMPLANT SYSTEM H 13 - 4,3 GREY
TH43G15	THEMYS IMPLANT SYSTEM H 15 - 4,3 GREY
TH43G18	THEMYS IMPLANT SYSTEM H 18 - 4,3 GREY
TH43G20	THEMYS IMPLANT SYSTEM H 20 - 4,3 GREY
TH43G22	THEMYS IMPLANT SYSTEM H 22 - 4,3 GREY
TH50B06	THEMYS IMPLANT SYSTEM H 06 - 5,0 BLUE
TH50B07	THEMYS IMPLANT SYSTEM H 07 - 5,0 BLUE
TH50B08	THEMYS IMPLANT SYSTEM H 08 - 5,0 BLUE
TH50B10	THEMYS IMPLANT SYSTEM H 10 - 5,0 BLUE
TH50B11	THEMYS IMPLANT SYSTEM H 11 - 5,0 BLUE
TH50B13	THEMYS IMPLANT SYSTEM H 13 - 5,0 BLUE
TH50B15	THEMYS IMPLANT SYSTEM H 15 - 5,0 BLUE



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PRODUCT CODE	ITEM DESCRIPTION
TH55Y08	THEMYS IMPLANT SYSTEM H 08 - 5,5 YELLOW
TH55Y10	THEMYS IMPLANT SYSTEM H 10 - 5,5 YELLOW
TH55Y11	THEMYS IMPLANT SYSTEM H 11 - 5,5 YELLOW
TH55Y13	THEMYS IMPLANT SYSTEM H 13 - 5,5 YELLOW
CE35V30	CEOS IMPLANT ZYGOMATIC H 30 - 3,5 VIOLET
CE35V32	CEOS IMPLANT ZYGOMATIC H 32,5 - 3,5 VIOLET
CE35V35	CEOS IMPLANT ZYGOMATIC H 35 - 3,5 VIOLET
CE35V37	CEOS IMPLANT ZYGOMATIC H 37,5 - 3,5 VIOLET
CE35V40	CEOS IMPLANT ZYGOMATIC H 40 - 3,5 VIOLET
CE35V42	CEOS IMPLANT ZYGOMATIC H 42,5 - 3,5 VIOLET
CE35V45	CEOS IMPLANT ZYGOMATIC H 45 - 3,5 VIOLET
CE35V47	CEOS IMPLANT ZYGOMATIC H 47,5 - 3,5 VIOLET
CE35V50	CEOS IMPLANT ZYGOMATIC H 50 - 3,5 VIOLET
CE35V52	CEOS IMPLANT ZYGOMATIC H 52,5 - 3,5 VIOLET
CE35V55	CEOS IMPLANT ZYGOMATIC H 55 - 3,5 VIOLET
CE35V57	CEOS IMPLANT ZYGOMATIC H 57,5 - 3,5 VIOLET
CE35V60	CEOS IMPLANT ZYGOMATIC H 60 - 3,5 VIOLET
CE42G30	CEOS IMPLANT ZYGOMATIC H 30 - 4,2 GREY
CE42G33	CEOS IMPLANT ZYGOMATIC H 32,5 - 4,2 GREY
CE42G35	CEOS IMPLANT ZYGOMATIC H 35 - 4,2 GREY
CE42G37	CEOS IMPLANT ZYGOMATIC H 37,5 - 4,2 GREY
CE42G40	CEOS IMPLANT ZYGOMATIC H 40 - 4,2 GREY
CE42G42	CEOS IMPLANT ZYGOMATIC H 42,5 - 4,2 GREY
CE42G45	CEOS IMPLANT ZYGOMATIC H 45 - 4,2 GREY
CE42G47	CEOS IMPLANT ZYGOMATIC H 47,5 - 4,2 GREY
CE42G50	CEOS IMPLANT ZYGOMATIC H 50 - 4,2 GREY
CE42G52	CEOS IMPLANT ZYGOMATIC H 52,5 - 4,2 GREY
CE42G55	CEOS IMPLANT ZYGOMATIC H 55 - 4,2 GREY
CE42G57	CEOS IMPLANT ZYGOMATIC H 57,5 - 4,2 GREY
CE42G60	CEOS IMPLANT ZYGOMATIC H 60 - 4,2 GREY



ANNEX 1 - PRODUCT CODES

PRODUCT CODE	ITEM DESCRIPTION
AB00H1LM	ESTETIC ABUTMENT - 0° - H1 LARGE VERSION MOLAR
AB00H1SI	ESTETIC ABUTMENT - 0° - H1 SMALL VERSION INCISAL
AB00H1SM	ESTETIC ABUTMENT - 0° - H1 SMALL VERSION MOLAR
AB00H2LI	ESTETIC ABUTMENT - 0° - H2 LARGE VERSION INCISAL
AB00H2LM	ESTETIC ABUTMENT - 0° - H2 LARGE VERSION MOLAR
AB00H2SI	ESTETIC ABUTMENT - 0° - H2 SMALL VERSION INCISAL
AB00H2SM	ESTETIC ABUTMENT - 0° - H2 SMALL VERSION MOLAR
AB00H3LI	ESTETIC ABUTMENT - 0° - H3 LARGE VERSION INCISAL
AB00H3LM	ESTETIC ABUTMENT - 0° - H3 LARGE VERSION MOLAR
AB00H3SI	ESTETIC ABUTMENT - 0° - H3 SMALL VERSION INCISAL
AB00H3SM	ESTETIC ABUTMENT - 0° - H3 SMALL VERSION MOLAR
AB17H1LI	ESTETIC ABUTMENT - 17° - H1 LARGE VERSION INCISAL
AB17H1LM	ESTETIC ABUTMENT - 17° - H1 LARGE VERSION MOLAR
AB17H1SI	ESTETIC ABUTMENT - 17° - H1 SMALL VERSION INCISAL
AB17H1SM	ESTETIC ABUTMENT - 17° - H1 SMALL VERSION MOLAR
AB17H2LI	ESTETIC ABUTMENT - 17° - H2 LARGE VERSION INCISAL
AB17H2LM	ESTETIC ABUTMENT - 17° - H2 LARGE VERSION MOLAR
AB17H2SI	ESTETIC ABUTMENT - 17° - H2 SMALL VERSION INCISAL
AB17H2SM	ESTETIC ABUTMENT - 17° - H2 SMALL VERSION MOLAR
AB17H3LI	ESTETIC ABUTMENT - 17° - H3 LARGE VERSION INCISAL
AB17H3LM	ESTETIC ABUTMENT - 17° - H3 LARGE VERSION MOLAR
AB17H3SI	ESTETIC ABUTMENT - 17° - H3 SMALL VERSION INCISAL
AB17H3SM	ESTETIC ABUTMENT - 17° - H3 SMALL VERSION MOLAR
AB25H1LI	ESTETIC ABUTMENT - 25° - H1 LARGE VERSION INCISAL
AB25H1LM	ESTETIC ABUTMENT - 25° - H1 LARGE VERSION MOLAR
AB25H1SI	ESTETIC ABUTMENT - 25° - H1 SMALL VERSION INCISAL
AB25H1SM	ESTETIC ABUTMENT - 25° - H1 SMALL VERSION MOLAR
AB25H2LI	ESTETIC ABUTMENT - 25° - H2 LARGE VERSION INCISAL
AB25H2LM	ESTETIC ABUTMENT - 25° - H2 LARGE VERSION MOLAR
AB25H2SI	ESTETIC ABUTMENT - 25° - H2 SMALL VERSION INCISAL
AB25H2SM	ESTETIC ABUTMENT - 25° - H2 SMALL VERSION MOLAR
AB25H3LI	ESTETIC ABUTMENT - 25° - H3 LARGE VERSION INCISAL
AB25H3LM	ESTETIC ABUTMENT - 25° - H3 LARGE VERSION MOLAR
AB25H3SI	ESTETIC ABUTMENT - 25° - H3 SMALL VERSION INCISAL
AB25H3SM	ESTETIC ABUTMENT - 25° - H3 SMALL VERSION MOLAR
BAH1	BALL ATTACHMENT - 3,5 - H1
BAH2	BALL ATTACHMENT - 3,5 - H2
CD-IL	CRICKET DRIVER INSERT LONG
CD-IS	CRICKET DRIVER INSERT SHORT
SD-A	SCREWDRIVER ADAPTER
CSB	COVER SCREW - BLUE
CSG	COVER SCREW - GREY
CSV	COVER SCREW - VIOLET
CSY	COVER SCREW - YELLOW
DIR-I	DIRECTION INDICATOR
DR-S	SHOULDER DRILL
FAH1	FLAT ATTACHMENT - 3,5 - H1
FAH2	FLAT ATTACHMENT - 3,5 - H2
FAH3	FLAT ATTACHMENT - 3,5 - H3
FD1109	LANCE DRILL
FD1308	DRILL TWIST 2,0 -6/15
FD1309	DRILL TWIST 2,0 10/18
FD1310	DRILL-TWIST 2,0 18/25
FD1311	DRILL TWIST 2,4-2,8 6/15
FD1312	DRILL TWIST 2,4-2,8 10/18
FD1313	DRILL-TWIST 2,4-2,8 18/25
FD1314/01	DRILL TWIST 2,8-3,2 6/15
FD1314/02	DRILL TWIST 3,0-3,4 6/15
FD1314/03	DRILL TWIST 3,2-3,7 6/15
FD1314/04	DRILL TWIST 3,8-4,2 6/15



ANNEX 1 - PRODUCT CODES

PRODUCT CODE	ITEM DESCRIPTION
FD1315/03	DRILL TWIST 3,2-3,7 10/18
FD1315/04	DRILL TWIST 3,8-4,2 10/18
FD1315/05	DRILL TWIST 3,4-3,9 10/18
FD1316/01	DRILL-TWIST 2,8-3,2 18/25
FD1316/02	DRILL-TWIST 3,0-3,4 18/25
FD1316/03	DRILL-TWIST 3,2-3,7 18/25
FD1316/03B	DRILL-TWIST 3,4-3,9 18/25
FD1316/04	DRILL-TWIST 3,8-4,2 18/25
FD1317/01	DRILL TWIST 4,2-4,6 6/15
FD1317/02	DRILL TWIST 4,2-5,0 6/15
FD1330/01	DRILL STOP 10 - 2-2,8
FD1330/02	DRILL STOP 11-18 - 2-2,8
FD1330/03	DRILL STOP 13-20 - 2-2,8
FD1330/04	DRILL STOP 15-22 - 2-2,8
FD1330/05	DRILL STOP 10 2,8-4,2
FD1330/06	DRILL STOP 11-18 2,8-4,2
FD1330/07	DRILL STOP 13-20 2,8-4,2
FD1330/08	DRILL STOP 15-22 2,8-4,2
FD1330/13	DRILL STOP 08 - 2-2,8
FD1330/14	DRILL STOP 08 2,8-4,2
FD1332/01	BONE MILL - 5,2 - VIOLET
FD1332/02	BONE MILL - 6,2 - GREY
FD1334/01	BONE MILL GUIDE
FD1335/01	DRILL-TAP SMALL - 3,55
FD1335/02	DRILL-TAP SMALL - 4,3
FD1335/03	DRILL-TAP SMALL - 5,0
FD1335/04	DRILL-TAP SMALL - 5,5
FD1336/01	DRILL-TAP LARGE - 3,55
FD1336/02	DRILL-TAP LARGE - 4,3
FD1336/03	DRILL-TAP LARGE - 5,0
FD1336/04	DRILL-TAP LARGE - 5,4
FD1558	MILLIMETRIC ZYGOMATIC PROBE
FD1578	DRILL-DLC 2,8-3,0
FD1579	DRILL-DLC 2,0-2,5-3,0
FD1580	DRILL-DLC 2,8-3,0
FD1581	DRILL-DLC 2,8-3,2
FD1582	DRILL-DLC 2,8-3,2
FD1583	DRILL-DLC 2,0-2,5-3,0
FD1584	DRILL-BALL BURR 4,2
FD1607/02	DRILL-KNURLED 4,2
FD1611	DRILL TWIST 2,0-2,5-3,0 L.60
FD1612	DRILL-DLC 2,0-2,5-3,0 L.80
FD1613	DRILL TWIST 2,8-3,0 L.60
FD1614	DRILL TWIST 2,8-3,0 L.80
FD1615	DRILL TWIST 2,8-3,2 L.60
FD1616	DRILL TWIST 2,8-3,2 L.80
HAH1L	HEALING ABUTMENT - 3,5 - H1 LARGE VERSION
HAH1S	HEALING ABUTMENT - 3,5 - H1 SMALL VERSION
HAH2L	HEALING ABUTMENT - 3,5 - H2 LARGE VERSION
HAH2S	HEALING ABUTMENT - 3,5 - H2 SMALL VERSION
HAH3L	HEALING ABUTMENT - 3,5 - H3 LARGE VERSION
HAH3S	HEALING ABUTMENT - 3,5 - H3 SMALL VERSION
UE-I	UNIVERSAL EXTENDER INSERT
IA35V	IMPLANT ANALOG VIOLET
IA43G	IMPLANT ANALOG GREY
IA50B	IMPLANT ANALOG BLUE
IA55Y	IMPLANT ANALOG YELLOW
I-SB	SCAN BODY IMPLANT
KIT-BS	SURGICAL KIT - BASIC
KIT-P	PROSTHETIC KIT



ANNEX 1 - PRODUCT CODES

PRODUCT CODE	ITEM DESCRIPTION
MUA00H1	MULTI-UNIT ABUTMENT - 0° - H1
MUA00H2	MULTI-UNIT ABUTMENT - 0° - H2
MUA00H3	MULTI-UNIT ABUTMENT - 0° - H3
MUA17H1	MULTI-UNIT ABUTMENT - 17° - H1
MUA17H2	MULTI-UNIT ABUTMENT - 17° - H2
MUA17H3	MULTI-UNIT ABUTMENT - 17° - H3
MUA30H1	MULTI-UNIT ABUTMENT - 30° - H1
MUA30H2	MULTI-UNIT ABUTMENT - 30° - H2
MUA30H3	MULTI-UNIT ABUTMENT - 30° - H3
MUA45H1	MULTI-UNIT ABUTMENT - 45° - H1
MUA45H2	MULTI-UNIT ABUTMENT - 45° - H2
MUA45H3	MULTI-UNIT ABUTMENT - 45° - H3
MUA53H1	MULTI-UNIT ABUTMENT - 53° - H1
MUA53H2	MULTI-UNIT ABUTMENT - 53° - H2
MUA53H3	MULTI-UNIT ABUTMENT - 53° - H3
MUA60H1	MULTI-UNIT ABUTMENT - 60° - H1
MUA60H2	MULTI-UNIT ABUTMENT - 60° - H2
MUA60H3	MULTI-UNIT ABUTMENT - 60° - H3
MUA-AN	MULTI UNIT ABUTMENT ANALOG
MUA-EX	MULTI UNIT ABUTMENT EXTRACTOR
MUA-HC5	MUA HEALING CAP 5
MUA-HC6	MUA HEALING CAP 6
MUA-HL	MULTI UNIT ABUTMENT HANDLE
MUA-SB	SCAN BODY MUA
MUA-TIB	MUA TI BASE
MUA-TIBS	MUA TI BASE UNIVERSAL SCREW
SD-E63	E63 SCREWDRIVER
SD-HD	SCREWDRIVER HEX DRIVER
SD-IL	SCREWDRIVER INSERT LONG
SD-I-MUA00	MUA 0° SCREWDRIVER INSERT
SD-IS	SCREWDRIVER INSERT SHORT
SD-L	SCREWDRIVER LONG
SD-S	SCREWDRIVER SHORT
SD-XL	SCREWDRIVER LAB XL
TDEX	TWIST DRILL EXTENSION
TIBH1NR	TI BASE ABUTMENT - H1 NOT ROTATING
TIBH1R	TI BASE ABUTMENT - H1 ROTATING
TIBH2NR	TI BASE ABUTMENT - H2 NOT ROTATING
TIBH2R	TI BASE ABUTMENT - H2 ROTATING
TIBH3NR	TI BASE ABUTMENT - H3 NOT ROTATING
TIBH3R	TI BASE ABUTMENT - H3 ROTATING
TCT-H1	TRANSFER CLOSED TRAY H1
TCT-H2	TRANSFER CLOSED TRAY H2
TCT-SH1	TRANSFER CLOSED TRAY SCREW H1
TCT-SH2	TRANSFER CLOSED TRAY SCREW H2
TOT-H1	TRANSFER OPEN TRAY H1
TOT-H2	TRANSFER OPEN TRAY H2
TOT-SH1	TRANSFER OPEN TRAY SCREW H1
TOT-SH2	TRANSFER OPEN TRAY SCREW H2
UCS	UNIVERSAL CLINICAL SCREW
WRADJ	ADJUSTABLE WRENCH
WRFX	FIXED WRENCH
HD-IE63	ZYGOMATIC HEX DRIVER INSERT E63