DICHIARAZIONE DI CONFORMITÀ UE 02/23

EU DECLARATION OF CONFORMITY 02/23

La Società IML SA con sede legale e operativa in Via Moree 16 – 6850 Mendrisio - Svizzera, in qualità di fabbricante dei dispositivi medici denominati "**accessori per impianti dentali**":
We undersigned IML SA with head office and operational headquarters addressed in Via Moree 16– 6850 Mendrisio - Switzerland, manufacturer of the following medical devices named "**Components for dental implants**"

Codice Ref. code	Descrizione / Denominazione Description/name	GMDN	Basic UDI-DI
CALI-U	MONCONE CALCINABILE NON ROTANTE ØU H2 / CALCINABLE NON ROTATING ABUTMENT ØU H2	44880	7640284147Q010207TV
TRA-U	TRANSFER OPEN TRAY ØU / OPEN TRAY IMPRESSION COPING ØU	44880	7640284147Q010207TV
MDIU-100	MONCONE PROVVISORIO DRITTO PEEK ØU H0 / PEEK TEMPORARY STRAIGHT ABUTMENT ØU H0	44880	7640284147Q010207TV
TRA-S	TRANSFER A STRAPPO CLOSED TRAY ØU / TEAR-OFF CLOSED TRAY IMPRESSION COPING ØU	44880	7640284147Q010207TV
TRA-SL	TRANSFER SLIM OPEN TRAY ØU / SLIM OPEN TRAY IMPRESSION COPING ØU	44880	7640284147Q010207TV
MIU15-100	MONCONE PROVVISORIO INCLINATO 15° PEEK ØU H0 / 15° ANGLED PEEK TEMPORARY ABUTMENT ØU H0	44880	7640284147Q010207TV
MDIU-101	MONCONE PROVVISORIO DRITTO ØU H0 / TEMPORARY STRAIGHT ABUTMENT ØU H0	44880	7640284147Q010207TV
TRA-P	TRANSFER PER PONTI OPEN TRAY ØU / BRIDGE OPEN TRAY IMPRESSION COPING ØU	44880	7640284147Q010207TV
TRA-C	TRANSFER CLOSED TRAY ØU / CLOSED TRAY IMPRESSION COPING ØU	44880	7640284147Q010207TV
CCIB-10	UNIVERSE IMPLANT DRIVER MULTITOOL H10 / BOX FOR SURGICAL INSTRUMENTS	33968	7640284147L159099VM
CCIB-15	UNIVERSE IMPLANT DRIVER MULTITOOL H15 / UNIVERSE MULTITOOL IMPLANT DRIVER H15	33968	7640284147L159099VM

CCIV-10	DRIVER MULTI- TOOL PER VITI H10 / MULTITOOL DRIVER FOR SCREWS H10	33968	7640284147L159099VM
CCIV-15	DRIVER MULTITOOL PER VITI H15 / MULTITOOL DRIVER FOR SCREWS H15	33968	7640284147L159099VM
CCP-0	PO/SO IMPLANT DRIVER MULTI- TOOL H0 / PO/SO MULTITOOL IMPLANT DRIVER H0	33968	7640284147L159099VM
CCP-10	PO/SO IMPLANT DRIVER MULTI- TOOL H10 / PO/SO MULTITOOL IMPLANT DRIVER H10	33968	7640284147L159099VM
CCP-15	PO/SO IMPLANT DRIVER MULTI- TOOL H15 / PO/SO MULTITOOL IMPLANT DRIVER H15	33968	7640284147L159099VM
CM-U	CACCIAVITE MANUALE MULTI- TOOL / MULTITOOL MANUAL DRIVER	33968	7640284147L159099VM
CCIB-25	UNIVERSE IMPLANT DRIVER MULTITOOL H25 / UNIVERSE MULTITOOL IMPLANT DRIVER H25	33968	7640284147L159099VM
AMM-U	DRIVER MULTI- TOOL PER MUA DRITTO / MULTITOOL DRIVER FOR STRAIGHT MUA	33968	7640284147L159099VM
UN-PIN	PIN DI PARALLELISMO / GUIDE PIN	57948	7640284147P01020180ZP
IMESTR-U1	UNIVERSE ESTRATTORE MULTITOOL PER MONCONI / UNIVERSE MULTITOOL REMOVER FOR ABUTMENT	45319	7640284147L159099VM
VITI-L	UNIVERSE VITE PER TRANSFER OPEN TRAY ØU / UNIVERSE SCREW FOR OPEN TRAY IMPRESSION COPING ØU	44880	7640284147P01020180ZP
VT-K	UNIVERSE VITE DI CONNESSIONE PER MONCONI PEEK E PROVVISORI / UNIVERSE CONNECTING SCREW FOR PEEK AND TEMPORARY ABUTMENT	44880	7640284147P01020180ZP
VITI-CT	UNIVERSE VITE DI CONNESSIONE PER TRANSFER CLOSED TRAY / UNIVERSE CONNECTING SCREW FOR IM- PRESSION COPING CLOSED TRAY	44880	7640284147P01020180ZP
SFYP005RP	TRANSFER OPEN TRAY RP / OPEN TRAY IMPRESSION COPING RP	44880	7640284147Q010207TV
SFYP007RP	TRANSFER CLOSED TRAY RP / CLOSED TRAY IMPRESSION COPING RP	44880	7640284147Q010207TV
SFYP046RP	MONCONE CALCINABILE NON ROTANTE RP H2 / CALCINABLE NON ROTATING ABUTMENT RP H2	44880	7640284147Q010207TV
SFYP047RP	MONCONE CALCINABILE ROTANTE RP H2 / CALCINABLE ROTATING ABUTMENT RP H2	44880	7640284147Q010207TV
SFYP062	CAPPETTA CHIUSA TITANIO PER PALLINA LARGE H4.1 / TITANIUM CLOSED CAP FOR	44880	7640284147Q010299UU

	LARGE BALL H4.1		
SFYP063	CAPPETTA APERTA TITANIO PER PALLINA LARGE H2.6 / TITANIUM OPEN CAP FOR LARGE BALL H2.6	44880	7640284147Q010299UU
SFYP076	TRANSFER OPEN TRAY PER MUA / UN/ST MUA OPEN TRAY IMPRESSION COPING	44880	7640284147Q010207TV
SFYP079	CILINDRO CALCINABILE PER MUA / UN/ST MUA CALCINABLE CYLINDER	44880	7640284147Q010207TV
SFYP100	CILINDRO SOVRAFUSIONE BASE Cr/Co PER MUA / UN/ST MUA Cr/Co BASE CALCI- NABLE CYLIN- DER	44880	7640284147Q010207TV
SFYP101	CILINDRO PROVVISORIO PEEK PER MUA / UN/ST MUA PEEK TEMPORARY CYLINDER	44880	7640284147Q010207TV
SFYP135RP	MONCONE PROVVISORIO NON ROTANTE RP H0 / TEMPORARY NON ROTATING ABUTMENT RP H0	44880	7640284147Q010207TV
SFYP136RP	MONCONE PROVVISORIO ROTANTE RP H0 / TEMPORARY ROTATING ABUTMENT RP H0	44880	7640284147Q010207TV
SFYP161	CAPPETTA PER FLEXATOR DA LABORA- TORIO - NERA- / FLEXATOR MID CAP FOR LAB -BLACK-	44880	7640284147Q010299UU
SFYP162	ANELLO SPAZIATORE PER FLEXATOR - BIANCO- / FLEXATOR BLOCK OUT SPACER -WHITE-	44880	7640284147P01020180ZP
SFYP164	TRANSFER PER FLEXATOR / FLEXATOR IMPRESSION COPING	44880	7640284147Q010207TV
SFYS001RP	STARFLY IMPLANT DRIVER MULTITOOL RP H12 / STARFLY MULTITOOL IMPLANT DRIVER RP H12	33968	7640284147L159099VM
SFYS002RP	STARFLY IMPLANT DRIVER MULTITOOL RP H17 / STARFLY MULTITOOL IMPLANT DRIVER RP H17	33968	7640284147L159099VM
SFYS017	STARFLY ESTRATTORE MULTI- TOOL PER MON- CONI FRICTION / STARFLY MULTI- TOOL REMOVER FOR FRIC- TION ABUT- MENT	45319	7640284147L159099VM
SFYS051	ADATTATORE DIGITALE PER DRIVER MULTITOOL / DIGITAL ADAPTER FOR MULTITOOL DRIVER	44880	7640284147L159099VM
SFYS065	DRIVER MULTITOOL PER FLEXATOR H6 / MULTITOOL DRIVER FOR FLEXATOR H6	33968	7640284147L159099VM
SFYS066	DRIVER MULTI- TOOL PER FLEXATOR H12 / MULTITOOL DRIVER FOR FLEXATOR H12	33968	7640284147L159099VM

SFYS067	DRIVER UNIVERSALE 3-in-1 FLEXATOR / FLEXATOR TOOL	33968	7640284147L159099VM
SFYS068	PIN DI PARALLELISMO PER FLEXATOR / FLEXATOR GUIDE PIN	57948	7640284147P01020180ZP
SFYV005	VITE DI CONNESSIONE TRANSFER CLOSED TRAY RP / CONNECTING SCREW FOR IM-PRESSION COPING CLOSED TRAY RP	44880	7640284147P01020180ZP
SFYV006	VITE DI CONNESSIONE TRANSFER OPEN TRAY RP / CONNECTING SCREW FOR IM-PRESSION COPING OPEN TRAY RP	44880	7640284147P01020180ZP
SFYV010	VITE DI CONNESSIONE PER TRANSFER OPEN TRAY PER MUA L15 / CONNECTING SCREW FOR IMPRESSION COPING OPEN TRAY FOR MUA L15	44880	7640284147P01020180ZP
SFYV011	VITE LUNGA PER TRANSFER PER MUA / LONG SCREW FOR MUA IMPRESSION COP-ING	44880	7640284147P01020180ZP
DN-I	CRICCHETTO DINAMOMETRICO / DYNA-MOMETRIC RATCHET	44901	7640284147L159099VM
CR-U	CRICCHETTO FISSO / FIXED RATCHET	44901	7640284147L159099VM
TRA-D	TRANSFER PER DISPARALLELISMO ØU / DISPARALLELISM IMPRESSION COPING ØU	44880	7640284147Q010207TV
VITI-DISP	UNIVERSE VITE DI CONNESSIONE ØU PER TRANSFER DISPARALLELISMO / UNIVERSE DISPARALLELISM CONNECTING SCREW FOR IMPRESSION COPING ØU	44880	7640284147P01020180ZP
VT-IMDR	UNIVERSE VITE DI CONNESSIONE IM-PLANT DRIVER ØU / UNIVERSE IMPLANT DRIVER CONNECTING SCREW ØU	44880	7640284147P01020180ZP
CCIB-GUID/T	UNIVERSE GUIDATA IMPLANT DRIVER MULTI-TOOL ØU – TITANIO / UNIVERSE GUIDED MULTITOOL IMPLANT DRIVER ØU -TITANIUM	33968	7640284147L159099VM
CCIB-GUID	UNIVERSE GUIDATA IMPLANT DRIVER MULTI-TOOL ØU - ACCIAIO CHIRURGICO / UNIVERSE GUIDED MULTITOOL IMPLANT DRIVER ØU -SURGICAL STEEL	33968	7640284147L159099VM
GCST	UNIVERSE GUIDA PER CRESTOTO- MO ØU /UNIVERSE BONE-CUTTER GUIDE ØU	44880	7640284147L159099VM
SFYP199RP	TRANSFER A STRAPPO CLOSED TRAY RP / TEAR-OFF CLOSED TRAY IMPRESSION COPING RP	44880	7640284147Q010207TV
SFYP201RP	TRANSFER OPEN TRAY PER DISPARALLEL-	44880	7640284147Q010207TV

	ISMO RP / DISPARALLELISM OPEN TRAY IMPRESSION COPING RP		
SFYP204RP	CAPPETTA STRAPPO PER TRANSFER / TEAR-OFF CAP FOR IMPRESSION COPING	44880	7640284147Q010299UU
SFYV049	VITE DI CONNESSIONE RP PER TRANSFER DI- SPARALLELISMO / CONNECTING SCREW FOR DISPARALLELISM IMPRESSION COPING RP	44880	7640284147P01020180ZP
SFYV051	VITE DI CONNESSIONE IMPLANT DRIVER RP / CONNECTING SCREW FOR IMPLANT DRIVER	44880	7640284147P01020180ZP
SFYS075RP	STARFLY GUIDATA IMPLANT DRIVER MULTITOOL RP – TITANIO / STARFLY GUIDED MULTITOOL IMPLANT DRIVER RP -TITANIUM	33968	7640284147L159099VM
SFYS088RP	STARFLY GUIDATA IMPLANT DRIVER MULTITOOL RP -ACCIAIO CHIRURGICO / STARFLY GUIDED MULTITOOL IMPLANT DRIVER RP -SURGICAL STEEL	33968	7640284147L159099VM
SFYS076RP	STARFLY GUIDA PER CRESTOTOMO RP / STARFLY BONE-CUTTER GUIDE RP	44880	7640284147L159099VM
SFYS077RP	STARFLY IMPLANT DRIVER CGF RP / STARFLY CGF IMPLANT DRIVER RP	33968	7640284147L159099VM
SFYS081	DRIVER MULTI-TOOL H10 PER VITE DINA-MICA / MULTITOOL DRIVER FOR DYNAMIC SCREW H10	33968	7640284147L159099VM
SFYS082	DRIVER MULTI-TOOL H15 PER VITE DINA-MICA / MULTITOOL DRIVER FOR DYNAMIC SCREW H15	33968	7640284147L159099VM
TRA29-S	TRANSFER CLOSED TRAY A STRAPPO / TEAR-OFF CLOSED TRAY IMPRESSION COP-ING	44880	7640284147Q010207TV
TRA29-D	TRANSFER OPEN TRAY PER DISPARALLEL-ISMO / DISPARALLELISM OPEN TRAY IMPRESSION COPING	44880	7640284147Q010207TV
VT29-IMDR	UNIVERSE 2.9 VITE DI CONNESSIONE IM-PLANT DRIVER / UNIVERSE 2.9 IMPLANT DRIVER CONNECTING SCREW	44880	7640284147P01020180ZP
VITI29-DISP	UNIVERSE 2.9 VITE DI CONNESSIONE PER TRANSFER DISPARALLELISMO / UNIVERSE 2.9 DISPARALLELISM CONNECT-ING SCREW FOR IMPRESSION COPING RP	44880	7640284147P01020180ZP
GCST29	UNIVERSE 2.9 GUIDA PER CRESTOTOMO /	44880	7640284147L159099VM

	UNIVERSE 2.9 BONE-CUTTER GUIDE RP		
CCIB29-GUID	UNIVERSE 2.9 GUIDATA IMPLANT DRIVER MULTITOOL - ACCIAIO CHIRURGICO / UNIVERSE 2.9 GUIDED MULTITOOL IMPLANT DRIVER -SURGICAL STEEL	33968	7640284147L159099VM
CCIB29-CGF	UNIVERSE 2.9 IMPLANT DRIVER CGF / UNIVERSE 2.9 CGF IMPLANT DRIVER RP	33968	7640284147L159099VM
GBG50	GUIDATA BOCCOLA GUIDA Ø5 / GUIDED BUSH-GUIDE Ø5	44880	7640284147L159099VM
GBG-01	GUIDATA BOCCOLA GUIDA PER PIN / GUIDED PIN BUSH-GUIDE	44880	7640284147L159099VM
BITGA	GUIDATA BITE GAUGE / GUIDED BITE GAUGE	44880	7640284147L159099VM
CALI29-25R	MONCONE CALCINABILE ROTANTE H2 / CALCINABLE ROTATING ABUTMENT H2	44880	7640284147Q010207TV
CALI29-2NR	MONCONE CALCINABILE NON ROTANTE H2 / CALCINABLE NON ROTATING ABUTMENT H2	44880	7640284147Q010207TV
CCIB29-10	UNIVERSE 2.9 IMPLANT DRIVER MULTI-TOOL H10 / UNIVERSE 2.9 MULTITOOL IMPLANT DRIVER H10	44880	7640284147L159099VM
CCIB29-15	UNIVERSE 2.9 IMPLANT DRIVER MULTI-TOOL H15 / UNIVERSE 2.9 MULTITOOL IMPLANT DRIVER H15	44880	7640284147L159099VM
CCIB29-25	UNIVERSE 2.9 IMPLANT DRIVER MULTI-TOOL H25 / UNIVERSE 2.9 MULTITOOL IMPLANT DRIVER H25	44880	7640284147L159099VM
IMESTR-29	UNIVERSE 2.9 ESTRATTORE MULTITOOL PER MONCONI / UNIVERSE 2.9 MULTITOOL REMOVER FOR ABUTMENT	45319	7640284147L159099VM
MDI29-100	MONCONE PROVVISORIO PEEK / PEEK TEMPORARY ABUTMENT	44880	7640284147Q010207TV
MDI29-101	MONCONE PROVVISORIO DRITTO NON ROTANTE / TEMPORARY NON ROTATING ABUTMENT	44880	7640284147Q010207TV
MDI29R-101	MONCONE PROVVISORIO DRITTO ROTANTE / TEMPORARY ROTATING ABUTMENT	44880	7640284147Q010207TV
TRA29-C	TRANSFER CLOSED TRAY / CLOSED TRAY IMPRESSION COPING	44880	7640284147Q010207TV
TRA29-U	TRANSFER OPEN TRAY / OPEN TRAY IMPRESSION COPING	44880	7640284147Q010207TV
VITI29-CT	UNIVERSE 2.9 VITE DI CONNESSIONE PER	44880	7640284147P01020180ZP

	TRANSFER CLOSED TRAY / UNIVERSE 2.9 CONNECTING SCREW FOR CLOSED TRAY IMPRESSION COPING		
VITI29-L	UNIVERSE 2.9 VITE DI CONNESSIONE PER TRANSFER OPEN TRAY H20 / UNIVERSE 2.9 CONNECTING SCREW FOR OPEN TRAY IMPRESSION COPING H20	44880	7640284147P01020180ZP
VITI29-S	UNIVERSE 2.9 VITE DI CONNESSIONE PER TRANSFER OPEN TRAY H15 / UNIVERSE 2.9 CONNECTING SCREW FOR OPEN TRAY IMPRESSION COPING H15	44880	7640284147P01020180ZP
VT29-K	UNIVERSE 2.9 VITE DI CONNESSIONE PER MONCONI PEEK / UNIVERSE 2.9 CONNECTING SCREW FOR PEEK ABUTMENT	44880	7640284147P01020180ZP
VITI29- ANICAD	UNIVERSE 2.9 VITE DI FISSAGGIO ANALOGO CAD- CAM 2.9 / UNIVERSE 2.9 UN/ST CAD-CAM FIXING SCREW FOR IMPLANT REPLICA	44880	7640284147P01020180ZP
CCIB29- GUID/T	UNIVERSE 2.9 GUIDATA IMPLANT DRIVER MUTITOOL – TITANIO / UNIVERSE 2.9 GUIDED MULTITOOL IMPLANT DRIVER - TITANIUM	33968	7640284147L159099VM
CCIB-CGF	UNIVERSE IMPLANT DRIVER CGF ØU / UNIVERSE CGF IMPLANT DRIVER ØU	33968	7640284147L159099VM
SFYS094RP	STARFLY GUIDATA IMPLANT DRIVER RITENTIVO MULTITOOL RP / STARFLY GUIDED MULTITOOL RETENTIVE IMPLANT DRIVER RP	33968	7640284147L159099VM
CCIB29-GUID/N	UNIVERSE 2.9 GUIDATA IMPLANT DRIVER RITENTIVO MULTITOOL / UNIVERSE 2.9 GUIDED MULTITOOL RETENTIVE IMPLANT DRIVER	33968	7640284147L159099VM
CCIB-GUID/N	UNIVERSE GUIDATA IMPLANT DRIVER RITENTIVO MULTITOOL ØU / UNIVERSE GUIDED MULTITOOL RETENTIVE IMPLANT DRIVER ØU	33968	7640284147L159099VM
ESYP006	EASY ANELLO SPAZIATORE PER FLEXATOR -BIANCO- (10PZ) / EASY FLEXATOR BLOCK OUT SPACER -WHITE-(10PCS)	44880	7640284147P01020180ZP
ESYP007	EASY CAPPETTA APERTA TITANIO PER PALLINA LARGE H2.6 / EASY TITANIUM OPEN CAP FOR LARGE BALL H2.6	44880	7640284147Q010299UU
ESYP008	EASY CAPPETTA CHIUSA TITANIO PER	44880	7640284147Q010299UU

	PALLINA LARGE H4.1 / EASY TITANIUM CLOSED CAP FOR LARGE BALL H4.1		
ESYP018	EASY CAPPETTA PER FLEXATOR PER LABORATORIO NERA / EASY FLEXATOR MID CAP FOR LAB -BLACK-	44880	7640284147Q010299UU
ESYP020	EASY CILINDRO CALCINABILE PER MUA / EASY MUA CALCINABLE CYLINDER	44880	7640284147Q010207TV
ESYP022	EASY CILINDRO SOVRAFUSIONE BASE Cr/Co PER MUA / EASY MUA Cr/Co BASE CALCINABLE CYLINDER	44880	7640284147Q010207TV
ESYP026RP	HEX RP EASY MONCONE CALCINABILE NON ROTANTE H2 / HEX RP EASY CALCINABLE NON ROTATING ABUTMENT H2	44880	7640284147Q010207TV
ESYP027RP	HEX RP EASY MONCONE CALCINABILE ROTANTE H2 / HEX RP EASY CALCINABLE ROTATING ABUTMENT H2	44880	7640284147Q010207TV
ESYP088RP	HEX RP EASY TRANSFER CLOSED TRAY / HEX RP EASY CLOSED TRAY IMPRESSION COPING	44880	7640284147Q010207TV
ESYP089	EASY TRANSFER OPEN TRAY PER MUA / EASY MUA OPEN TRAY IMPRESSION COPING	44880	7640284147Q010207TV
ESYP090RP	HEX RP EASY TRANSFER OPEN TRAY / HEX RP EASY OPEN TRAY IMPRESSION COPING	44880	7640284147Q010207TV
ESYP091	EASY TRANSFER PER FLEXATOR / EASY FLEXATOR IMPRESSION COPING	44880	7640284147Q010207TV
ESYP092RP	HEX RP EASY TRANSFER A STRAPPO / HEX RP EASY TEAR-OFF CLOSED TRAY IMPRESSION COPING	44880	7640284147Q010207TV
DN-E	EASY CRICCHETTO DINAMOMETRICO / EASY DYNAMOMETRIC RATCHET	44901	7640284147L159099VM
ESYS018	EASY DRIVER MULTITOOL PER FLEXATOR H12 / EASY MULTITOOL DRIVER FOR FLEXATOR H12	33968	7640284147L159099VM
ESYS019	EASY DRIVER MULTITOOL PER FLEXATOR H6 / EASY MULTITOOL DRIVER FOR FLEXATOR H6	33968	7640284147L159099VM
ESYS020	EASY DRIVER MULTITOOL PER VITE DINAMICA H10 / EASY MULTITOOL DRIVER FOR DYNAMIC SCREW H10	33968	7640284147L159099VM
ESYS021	EASY DRIVER MULTITOOL PER VITE DINAMICA H15 / EASY MULTITOOL DRIVER	33968	7640284147L159099VM

	FOR DYNAMIC SCREW H15		
ESYS022	EASY DRIVER UNIVERSALE 3-IN-1 PER FLEXATOR / EASY FLEXATOR 3-in-1 UNIVERSAL DRIVER	33968	7640284147L159099VM
ESYS035RP	HEX RP EASY IMPLANT DRIVER MULTITOOL H12 / HEX RP EASY MULTITOOL IMPLANT DRIVER H12	33968	7640284147L159099VM
ESYS036RP	HEX RP EASY IMPLANT DRIVER MULTITOOL H17 / HEX RP EASY MULTITOOL IMPLANT DRIVER H17	33968	7640284147L159099VM
ESYS039	EASY PIN DI PARALLELISMO PER FLEXATOR / EASY FLEXATOR GUIDE PIN	57948	7640284147P01020180ZP
ESYV001	EASY VITE DI CONNESSIONE DINAMICA PER MUA (5PZ) / EASY DYNAMIC CONNECTING SCREW FOR MUA 5 PCS	44880	7640284147P01020180ZP
ESYV007	EASY VITE DI CONNESSIONE PER TRANSFER OPEN TRAY PER MUA L15 / EASY CONNECTING SCREW FOR IMPRESSION COPING OPEN TRAY FOR MUA L15	44880	7640284147P01020180ZP
ESYV008	EASY VITE DI CONNESSIONE TRANSFER CLOSED TRAY RP / EASY CONNECTING SCREW FOR IMPRESSION COPING CLOSED TRAY RP	44880	7640284147P01020180ZP
ESYV009	EASY VITE DI CONNESSIONE TRANSFER OPEN TRAY RP / EASY CONNECTING SCREW FOR IMPRESSION COPING OPEN TRAY RP	44880	7640284147P01020180ZP
ESYV010	EASY VITE DI FISSAGGIO ANALOGO CAD-CAM / EASY CAD-CAM FIXING SCREW FOR IMPLANT REPLICA	44880	7640284147Q010207TV
ESYV022	EASY VITE DI CONNESSIONE DINAMICA RP (5PZ) / EASY DYNAMIC CONNECTING SCREW (5PCS)	44880	7640284147P01020180ZP

Destinati ad essere strumenti ed accessori per impianti dentali di classe di rischio I, in accordo alla **regola 5** dell'Allegato VIII del Regolamento UE 2017/745, dichiara sotto la propria totale esclusiva responsabilità, che tali dispositivi:

Intended to be instruments and accessories for dental implants, risk class I, in accordance with **rule 5** of Annex VIII of EU Regulation 2017/745, declares under its sole responsibility that these devices:

- sono conformi ai requisiti generali di sicurezza e prestazione ed alle disposizioni del Regolamento (UE) 2017/745 e ss.mm.ii. come da Fascicolo Tecnico archiviato presso l'azienda;

- comply with the general safety and performance requirements and the provisions of Regulation (EU) 2017/745 and subsequent amendments and integrations. as per the Technical File filed at the company;
- non sono state utilizzate Specifiche Comuni per la conformità dei dispositivi;
- Common Specifications have not been used for the compliance of the devices;
- sono fabbricati in accordo al Fascicolo Tecnico, che soddisfa i requisiti di cui all'Allegato II e III del sopra citato Regolamento;
- are manufactured in accordance with the Technical File, which meets the requirements set out in Annex II and III of the aforementioned Regulation;
- il rappresentante Europeo è la società IML ITALIA S.r.l. (SRN: IT-AR-000032507) con sede legale e operativa in Via Leonardo da Vinci 43, 20090 Trezzano sul Naviglio (MI)
- the European representative is the company IML ITALIA S.r.l. (SRN: IT-AR-000032507) with registered and operational headquarters in Via Leonardo da Vinci 43, 20090 Trezzano sul Naviglio (MI).

Mendrisio (CH), 2023 September 21st

Legale Rappresentante
Legal Representative
(Giovanni Canino)