DICHIARAZIONE DI CONFORMITÀ UE 05/23

EU DECLARATION OF CONFORMITY 05/23

La Società IML SA con sede legale e operativa in Via Moree 16 – 6850 Mendrisio - Svizzera, in qualità di fabbricante dei dispositivi medici denominati "**Strumentario dentale**":

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 "**Dental Instrument**"

Nome del prodotto/Categoria **Product name/Category**	**UDI-DI di base** **Basic UDI-DI**
Frese Drills	764028414DRILLC7
Prolunghe per frese Dental drill extension	764028414PROLFRESCY
Driver	764028414DRIVEU
Stop di profondità Depth stop	764028414STOPJM
Maschiatori Threadformers	764028414MASCHC2
Pin di fissaggio Fixing Pin	764028414PINM3

Codice **Ref. code**	**Descrizione / Denominazione** **Description/name**	**Misura** **Size**	**Classe di rischio** **Risk class**	**GMDN**
FC34-6	FRESA CONICA / CONICAL DRILL	D.3.4 H.6	IIa	45714
FC34-8	FRESA CONICA / CONICAL DRILL	D.3.4 H.8	IIa	45714
FC34-10	FRESA CONICA / CONICAL DRILL	D.3.4 H.10	IIa	45714
FC34-11.5	FRESA CONICA / CONICAL DRILL	D.3.4 H.11.5	IIa	45714
FC34-13	FRESA CONICA / CONICAL DRILL	D.3.4 H.13	IIa	45714
FC34-15	FRESA CONICA / CONICAL DRILL	D.3.4 H.15	IIa	45714

FC40-6	FRESA CONICA / CONICAL DRILL	D.4.0 H.6	IIa	45714
FC40-8	FRESA CONICA / CONICAL DRILL	D.4.0 H.8	IIa	45714
FC40-10	FRESA CONICA / CONICAL DRILL	D.4.0 H.10	IIa	45714
FC40-11.5	FRESA CONICA / CONICAL DRILL	D.4.0 H.11.5	IIa	45714
FC40-13	FRESA CONICA / CONICAL DRILL	D.4.0 H.13	IIa	45714
FC40-15	FRESA CONICA / CONICAL DRILL	D.4.0 H.15	IIa	45714
FC45-6	FRESA CONICA / CONICAL DRILL	D.4.5 H.6	IIa	45714
FC45-8	FRESA CONICA / CONICAL DRILL	D.4.5 H.8	IIa	45714
FC45-10	FRESA CONICA / CONICAL DRILL	D.4.5 H.10	IIa	45714
FC45-11.5	FRESA CONICA / CONICAL DRILL	D.4.5 H.11.5	IIa	45714
FC45-13	FRESA CONICA / CONICAL DRILL	D.4.5 H.13	IIa	45714
FC45-15	FRESA CONICA / CONICAL DRILL	D.4.5 H.15	IIa	45714
FC50-6	FRESA CONICA / CONICAL DRILL	D.5.0 H.6	IIa	45714
FC50-8	FRESA CONICA / CONICAL DRILL	D.5.0 H.8	IIa	45714
FC50-10	FRESA CONICA / CONICAL DRILL	D.5.0 H.10	IIa	45714
FC50-11.5	FRESA CONICA / CONICAL DRILL	D.5.0 H.11.5	IIa	45714
FC50-13	FRESA CONICA / CONICAL DRILL	D.5.0 H.13	IIa	45714
FC50-15	FRESA CONICA / CONICAL DRILL	D.5.0 H.15	IIa	45714
FC60-6	FRESA CONICA / CONICAL DRILL	D.6.0 H.6	IIa	45714
FC60-8	FRESA CONICA / CONICAL DRILL	D.6.0 H.8	IIa	45714
FL30-U	FRESA CILINDRICA / CYLINDRICAL DRILL	D.2.0 H.U	IIa	45714

F105-1	FRESA LANCEOLATA / PRECISION DRILL	D.0.5 H.U	IIa	45714
SFYS18	FRESA LANCEOLATA / PRECISION DRILL	D.0.5 H.U	IIa	45714
PR-FR	PROLUNGA PER FRESA / DENTAL DRILL EXTENSION	-	IIa	45320
SFYS003RP	IMPLANT DRIVER DA MOTORE RP / IMPLANT DRIVER FOR MOTOR RP	H.12	IIa	47829
SFYS004RP	IMPLANT DRIVER DA MOTORE RP / IMPLANT DRIVER FOR MOTOR RP	H.17	IIa	47829
SFYS011	DRIVER DA MOTORE PER VITI / MOTOR DRIVER FOR SCREWS	H.6	IIa	47829
SFYS012	DRIVER DA MOTORE PER VITI / MOTOR DRIVER FOR SCREWS	H.12	IIa	47829
SFYS013	DRIVER DA MOTORE PER VITI / MOTOR DRIVER FOR SCREWS	H.17	IIa	47829
SFYS016	DRIVER DA MOTORE PER MUA DRITTO / MOTOR DRIVER FOR STRAIGHT MUA	-	IIa	47829
SFYS063	DRIVER DA MOTORE PER FLEXATOR / MOTOR DRIVER FOR FLEXATOR	H.6	IIa	47829
SFYS064	DRIVER DA MOTORE PER FLEXATOR / MOTOR DRIVER FOR FLEXATOR	H.12	IIa	47829
SFYS019	FRESA PILOTA / PILOT DRILL	D.2	IIa	45714

SFYS19	FRESA PILOTA / PILOT DRILL	D.2	IIa	45714
SFYS020	ST/PO FRESA CILINDRICA / CYLINDRICAL DRILL	D.2.4	IIa	45714
SFYS021	FRESA CILINDRICA / CYLINDRICAL DRILL	D.2.7	IIa	45714
SFYS022	FRESA CILINDRICA / CYLINDRICAL DRILL	D.3.1	IIa	45714
SFYS023	FRESA CILINDRICA / CYLINDRICAL DRILL	D.3.6	IIa	45714
SFYS024	FRESA CILINDRICA / CYLINDRICAL DRILL	D.4.0	IIa	45714
SFYS025	FRESA CILINDRICA / CYLINDRICAL DRILL	D.4.4	IIa	45714
SFYS026	FRESA CILINDRICA / CYLINDRICAL DRILL	D.5.3	IIa	45714
SFYS20	FRESA CILINDRICA / CYLINDRICAL DRILL	D.3.9 H.U	IIa	45714
SFYS55	FRESA CILINDRICA / CYLINDRICAL DRILL	D.4.9 H.U	IIa	45714
SFYS21	FRESA CILINDRICA / CYLINDRICAL DRILL	D.2.7 H.U	IIa	45714
SFYS22	FRESA CILINDRICA / CYLINDRICAL DRILL	D.3.1 H.U	IIa	45714

SFYS23	FRESA CILINDRICA / CYLINDRICAL DRILL	D.3.6 H.U	IIa	45714
SFYS24	FRESA CILINDRICA / CYLINDRICAL DRILL	D.4.0 H.U	IIa	45714
SFYS25	FRESA CILINDRICA / CYLINDRICAL DRILL	D.4.4 H.U	IIa	45714
SFYS26	FRESA CILINDRICA / CYLINDRICAL DRILL	D.5.3 H.U	IIa	45714
SFYS028	COUNTERSINK	D.3.5	IIa	45714
SFYS029	COUNTERSINK	D.4	IIa	45714
SFYS030	COUNTERSINK	D.4.5	IIa	45714
SFYS031	COUNTERSINK	D.5	IIa	45714
SFYS032	COUNTERSINK	D.6	IIa	45714
SFYS042	KIT BUSSOLA STOP / STOP DRILL KIT	-	IIa	47829
SFYS043	BUSSOLA STOP / STOP DRILL	D.5.0. H.11.5	IIa	47829
SFYS040	BUSSOLA STOP VERDE H6 PER FRESE DA Ø4.4 / GREEN DRILL STOP H6 FOR DRILLS FROM Ø4.4	-	IIa	47829
SFYS052	POWER BUSSOLA STOP VERDE H6 PER FRESE Ø4.4-5.3/ POWER GREEN DRILL STOP H6 FOR DRILLS Ø4.4-5.3	-	IIa	47829
AVM-C	AVVITATORE PER MICROMOTORE / MICROMOTORS SCREWER. IMM. IMPL. SHORT	-	IIa	47829

AVM-L	AVVITATORE PER MICROMOTORE / MICROMOTORS SCREWER. IMM. IMPL. LONG	-	IIa	47829
AVP-C	AVVITATORE PER MICROMOTORE / MICROMOTORS SCREWER. P/S IMPL. SHORT	-	IIa	47829
AVP-L	AVVITATORE PER MICROMOTORE / MICROMOTORS SCREWER. P/S IMPL. LONG	-	IIa	47829
STF-KIT	KIT STOP PER FRESA / DRILL STOP KIT	-	IIa	47829
MC34	MASCHIATORE / THREADFORMERS	D.3.4	Ir	47829
MC40	MASCHIATORE / THREADFORMERS	D.4	Ir	47829
MC45	MASCHIATORE / THREADFORMERS	D.4.5	Ir	47829
MC50	MASCHIATORE / THREADFORMERS	D.5	Ir	47829
FC29-2	FRESA PILOTA CILINDRICA Ø2.0 / CYLINDRICAL PILOT DRILL Ø2.0	D.2	IIa	45714
FC29-28	FRESA CILINDRICA Ø2.8 / CYLINDRICAL DRILL Ø2.8	D.2.8	IIa	45714
MC29-U	MASCHIATORE / THREADFORMER	-	Ir	47829
STF29-KIT	KIT BUSSOLE STOP PER FRESE Ø2-2-8 / KIT DRILL STOPS FOR DRILL Ø2-2.8	-	IIa	45714
AVM29-10	IMPLANT DRIVER DA MOTORE H10 / IMPLANT DRIVER FOR MOTOR H10	H.10	IIa	47829
AVM29-15	IMPLANT DRIVER DA MOTORE H15 / IMPLANT DRIVER FOR MOTOR H15	H.15	IIa	47829
AVM29-25	IMPLANT DRIVER DA MOTORE H25 / IMPLANT DRIVER FOR MOTOR H25	H.25	IIa	47829
SFYS078	CRESTOTOMO / BONE-CUTTER	D.4.2	IIa	10455

SFYS079	CRESTOTOMO / BONE-CUTTER	D.5.5	IIa	10455
SFYS080	CRESTOTOMO / BONE-CUTTER	-	IIa	10455
SFYS083	DRIVER DA MOTORE PER VITE DINAMICA / MOTOR DRIVER FOR DYNAMIC SCREW	H.6	IIa	47829
SFYS084	DRIVER DA MOTORE PER VITE DINAMICA / MOTOR DRIVER FOR DYNAMIC SCREW	H.12	IIa	47829
SFYS085	DRIVER DA MOTORE PER VITE DINAMICA / MOTOR DRIVER FOR DYNAMIC SCREW	H.17	IIa	47829
SFYS086	COUNTERSINK	D.3.8	IIa	45714
INYS001	MASCHIATORE / THREADFORMERS	D.3.3	Ir	47829
INYS002	MASCHIATORE / THREADFORMERS	D.3.8	Ir	47829
INYS003	MASCHIATORE / THREADFORMERS	D.4.2	Ir	47829
INYS004	MASCHIATORE / THREADFORMERS	D.4.6	Ir	47829
INYS005	MASCHIATORE / THREADFORMERS	D.5.2	Ir	47829
GFF15	FRESA DI FISSAGGIO PIN / PIN FIXING-DRILL	D.1.5	IIa	45714
GPF-01	PIN DI FISSAGGIO DIMA/ MOULD-FIXING PIN	-	Ir	47829
GMU-01	MUCOTOMO / MUCOTOME	-	IIa	45329
GFI-01	FRESA INIZIALE/ STARTING DRILL	-	IIa	45714
GFR20-6	FRESA / DRILL	D.2.0 H.6	IIa	45714
GFR20-8	FRESA / DRILL	D.2.0 H.8	IIa	45714
GFR20-10	FRESA / DRILL	D.2.0 H.10	IIa	45714
GFR20-11.5	FRESA / DRILL	D.2.0 H.11.5	IIa	45714

GFR20-13	FRESA / DRILL	D.2.0 H.13	IIa	45714
GFR20-15	FRESA / DRILL	D.2.0 H.15	IIa	45714
GFR28-6	FRESA / DRILL	D.2.8 H.6	IIa	45714
GFR28-8	FRESA / DRILL	D.2.8 H.8	IIa	45714
GFR28-10	FRESA / DRILL	D.2.8 H.10	IIa	45714
GFR28-11.5	FRESA / DRILL	D.2.8 H.11.5	IIa	45714
GFR28-13	FRESA / DRILL	D.2.8 H.13	IIa	45714
GFR28-15	FRESA / DRILL	D.2.8 H.15	IIa	45714
GFR31-6	FRESA / DRILL	D.3.1 H.6	IIa	45714
GFR31-8	FRESA / DRILL	D.3.1 H.8	IIa	45714
GFR31-10	FRESA / DRILL	D.3.1 H.10	IIa	45714
GFR31-11.5	FRESA / DRILL	D.3.1 H.11.5	IIa	45714
GFR31-13	FRESA / DRILL	D.3.1 H.13	IIa	45714
GFR31-15	FRESA / DRILL	D.3.1 H.15	IIa	45714
GFR36-6	FRESA / DRILL	D.3.6 H.6	IIa	45714
GFR36-8	FRESA / DRILL	D.3.6 H.8	IIa	45714
GFR36-10	FRESA / DRILL	D.3.6 H.10	IIa	45714
GFR36-11.5	FRESA / DRILL	D.3.6 H.11.5	IIa	45714
GFR36-13	FRESA / DRILL	D.3.6 H.13	IIa	45714
GFR36-15	FRESA / DRILL	D.3.6 H.15	IIa	45714
GFR40-6	FRESA / DRILL	D.4.0 H.6	IIa	45714
GFR40-8	FRESA / DRILL	D.4.0 H.8	IIa	45714

GFR40-10	FRESA / DRILL	D.4.0 H.10	IIa	45714
GFR40-11.5	FRESA / DRILL	D.4.0 H.11.5	IIa	45714
GFR40-13	FRESA / DRILL	D.4.0 H.13	IIa	45714
GFR40-15	FRESA / DRILL	D.4.0 H.15	IIa	45714
GCK29	COUNTERSINK	D.2.9	IIa	45714
GCK35	COUNTERSINK	D.3.5	IIa	45714
GCK38	COUNTERSINK	D.3.8	IIa	45714
GCK40	COUNTERSINK	D.4.0	IIa	45714
GCK45	COUNTERSINK	D.4.5	IIa	45714

Destinati alla formazione della cava implantare mascellare o mandibolare su cui andranno ad alloggiare gli impianti dentali di classe di rischio IIa e Ir, in accordo alla regola 6 dell'Allegato VIII del Regolamento UE 2017/745, dichiara sotto la propria totale esclusiva responsabilità, che tali dispositivi:

Intended for the formation of the maxillary or mandibular implant cavity in which the dental implants will be housed. Of risk class IIa and Ir, in accordance with rule 6 of Annex VIII of EU Regulation 2017/745, declares under its total exclusive responsibility, that these devices:

- Sono conformi ai requisiti generali di sicurezza e prestazione ed alle disposizioni del Regolamento (UE) 2017/745 come da Documentazione Tecnica presente in Azienda e depositata presso l'ente;
  Comply with the general safety and performance requirements and with the provisions of Regulation (EU) 2017/745 as per the Technical Documentation present in the Company and deposited to the institution;
- Non sono state utilizzate Specifiche Comuni per la conformità dei dispositivi;
  Common Specifications have not been used for device compliance;
- Sono fabbricati in accordo al Fascicolo Tecnico n. FT 002 IML, che soddisfa i requisiti di cui all'Allegato IX, capo I del sopra citato Regolamento, come da Certificato n. 0425-MDR-030034-01, rilasciato da ICIM S.p.A con sede in Italia a Sesto San

Giovanni (MI) in Piazza Don Enrico Mapelli, 75, Organismo Notificato 0425, il 13 giugno 2023 con scadenza 12 Giugno 2028.
Are manufactured in accordance with the Technical File n. FT 002 IML, which satisfies the requirements of Annex IX, chapters I of the aforementioned Regulation, as per Certificate no. 0425-MDR-030034-01, issued by ICIM S.p.A with headquarters in Italy in Sesto San Giovanni (MI) in Piazza Don Enrico Mapelli, 75, Notified Body 0425, on 13 June 2023 with expiry on 12 June 2028.

Il mandatario è la società:
The European Representative is the company:

IML ITALA S.r.l. (code SRN: *IT-AR-000032507*)
Via L. Da Vinci, 43
Trezzano sul Naviglio (MI)
ITALY

Mendrisio (CH), 2023 September 21st

IML SA
Il legale Rappresentante
The legal Representative
(Giovanni Canino)