GIMA S.p.A.
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www.gimaitaly.com

ITALIAN DIVISION
gima@gimaitaly.com
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EU DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A. (single registration number (SRN): IT-MF-000011004), with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milan, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

Product and trade name	Product code	Basic UDI-DI	Intended purpose	Rule
EXPLORER PROBE	60100	802327900L1590030000000WC	to explore and/or perform therapeutic procedures during various types of dental surgical intervention	5
EXPLORER - fig.17/23	60101	802327900L1590030000000WC		5
WHO PROBE	60105	802327900L1590030000000WC		5
Mc CALL CURETTE - fig.13/14	60120	802327900L1590010000000V6		5
GRACEY CURETTE - fig.1/2 ant.	60125	802327900L1590010000000V6		5
GRACEY CURETTE - fig.7/8 medium	60127	802327900L1590010000000V6		5
GRACEY CURETTE - fig.11/12 medium	60130	802327900L1590010000000V6		5
GRACEY CURETTE - fig.13/14 post.	60131	802327900L1590010000000V6		5
SCALER - fig.1	60140	802327900L1590994800000DU	removing calculus and other accretions from the surface and between the teeth during dental cleaning and periodontal (gum) therapy	5
Mc CALL SCALER - fig.18	60141	802327900L1590994800000DU		5
MITCHEL SCALER	60142	802327900L1590994800000DU		5
LANGER SCALER - fig.1/2	60144	802327900L1590994800000DU		5
LANGER SCALER - fig.3/4	60145	802327900L1590994800000DU		5
HYGIENIST SCALER - fig. H6/7	60148	802327900L1590994800000DU		5
SCALER fig. 204S	60150	802327900L1590994800000DU		5
PERIODONTIA INSTR. - fig. ST 2/3	60155	802327900L1590995700000DY	to explore and/or perform therapeutic procedures during various types of dental surgical intervention	5
PERIODONTIA INSTR.	60156	802327900L1590995700000DY		5
CEMENT SPATULA	60170	802327900L159013530000032	used by dentists to apply, remove and mix dental cements	5
WILAND MODELLING CARVER	60171	802327900L15901758000007F	to explore and/or perform therapeutic procedures during various types of dental surgical intervention	5
INTERPROXIMAL MODELLING CARVER	60172	802327900L15901758000007F		5
BEALE MODELLING CARVER - mod. 7A	60173	802327900L15901758000007F		5

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FAHNENSTOCK MODELLING CARVER - 13 cm	60174	802327900L15901758000007F		5
CARTRIDGE SYRINGE - 2.2 cc	60195	802327900A020203000000003W	used to inject an anesthetic agent, subcutaneously or intramuscularly, from a pre-filled disposable cartridge through an attached sterile needle; needle not included	2
AMALGAM CARRIER	60210	802327900L1590994200000BE	designed to collect, transport and deposit amalgam in its plastic state into prepared cavities	1

risk class I (not sterile), in accordance with the rules set out in Annex VIII of the Regulation (EU) 2017/745 (MDR), declares, under its sole responsibility, that this device:

- complies with the Regulation (EU) 2017/745 (MDR);
- Common Specifications have not been used for the compliance of the above medical device.

Gessate, 30/06/2026

GIMA S.p.A.
The legal
Representative
(Nicola Manzoni)