

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
ALUMINIUM TUNING FORK 128 Hz	31225	802327900V0302088700020BM
ALUMINIUM TUNING FORK 128 Hz - with foot	31226	802327900V0302088700020BM
DIAPASON HARTMANN 128 Hz	31230	802327900V0302088700100BL
DIAPASON HARTMANN 256 Hz	31231	802327900V0302088700100BL
DIAPASON HARTMANN 512 Hz	31232	802327900V0302088700100BL
DIAPASON HARTMANN 1024 Hz	31233	802327900V0302088700100BL
DIAPASON HARTMANN 2048 Hz	31234	802327900V0302088700100BL
DIAPASON HARTMANN 4096 Hz	31235	802327900V0302088700100BL
SET DIAPASON HARTMANN - 5 pcs.	31240	802327900V0302088700100BL
DIAPASON A1 440 NEURO	31245	802327900V0302088700100BL
DIAPASON LUCAS CH 28	31246	802327900V0302088700100BL
DIAPASON RYDEL-SEIFFER 64/128	31247	802327900V0302088700100BL
BUCK CLASSIC - neurological hammer	31251	802327900L1601010000000NH
BUCK COLOUR - neurological hammer - yellow	31252	802327900L1601010000000NH
DEJERINE CLASSIC - neurological hammer	31254	802327900L1601010000000NH
DEJERINE COLOUR - neurological hammer - red	31255	802327900L1601010000000NH
BABINSKY - neurological hammer	31256	802327900L1601010000000NH
QUEENS - neurological hammer	31257	802327900L1601010000000NH
TROEMNER - neurological hammer	31258	802327900L1601010000000NH
CHROME PLATED PINWHEEL	31260	802327900L1601014700000TG
NEUROLOGICAL KIT - 3 hammers	31265	802327900L1601010000000NH
BUCK BLACK EDITION - neurological hammer	31266	802327900L1601010000000NH
DEJERINE BLACK EDITION - neurological hammer	31267	802327900L1601010000000NH
BABINSKY BLACK EDITION - neurological hammer	31268	802327900L1601010000000NH
BUCK GIMA 2000 - neurological hammer	31270	802327900L1601010000000NH
DEJERINE GIMA 2000 - neurological hammer	31271	802327900L1601010000000NH
BABINSKY GIMA 2000 - neurological hammer	31272	802327900L1601010000000NH
TAYLOR HAMMER	31273	802327900L1601010000000NH

intended purpose:

- Neurological hammers/reflexology: assess the patient's alertness by gently but precisely striking areas that, once stimulated, produce a reflex response useful for assessing neuronal integrity.
- Tuning fork: used for various acumetric tests (Rinnie, Weber, etc.), which test sensitivity to sound, which is transmitted both through the air (COA) and bone (CO).

risk class I (not sterile), in accordance with the rule 1 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, 02/04/2026

GIMA S.p.A.

The legal Representative
(Nicola Manzoni)

