



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
PEDIATRIC TONGUE DEPRESSORS - plastic	25505	80232790000V900100BB0306J
MAYO S.S. TONGUE DEPRESSOR	25620	802327900L14909900000007B
BRUENING S.S. TONGUE DEPRESSOR - fenestrated	25621	802327900L14909900000007B
TOBOLD S.S. TONGUE DEPRESSOR	25623	802327900L14909900000007B

intended purpose: Intended for use during medical examinations of the oropharyngeal and auricular cavity

risk class I (not sterile), in accordance with the rule 5 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, 06/09/2023

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

A handwritten signature in black ink, appearing to read 'N. Manzoni', is written over a horizontal line.