GIMA S.p.A. Via Marconi, 1 20060 Gessate (MI) –Italy www.gimaitaly.com



ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

## **DECLARATION OF CONFORMITY**

We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

GIMA Single Registration Number (SRN):

Medical Device ( Trade Name and description)	Code	Basic UDI-DI code
MINI EAR SPECULUM diameter 2.5 mm - black	31491	802327900Q0304997500000C9

Risk class I (Not sterile), according to the Rule 5 Annex VIII of Regulation (EU) 2017/745 (MDR), declares, under its own responsibility, that this medical device:

- comply with essential requirements and dispositions of Regulation (EU) 2017/745 (MDR), as from the Technical File filed at the company;
- common Specifications have not been used for the compliance of the above medical device;

Gessate, 5/28/2021

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