



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
AMNIOSCOPE TUBE 12x24x200 mm.	29971	8023279Z1202908562000008H

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)

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