



## 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
LED "SPIRIT" TORCH - metal	25641	80232790000L17996800000ZA

intended purpose: intended to generate cold light for endoscopy and headlamps, for diagnostic examinations and minor surgery, and for illuminating the throat, pupils and ears of patients

risk class I (not sterile), in accordance with the rule 13 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;
- complies with Directive 2011/65/EU (and subsequent amendments and integrations) and COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Gessate, 18/12/2023

**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.