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Declaration statement

To Whom It May Concern:

We, Besmed Health Business Corporation, located at No. 5, Lane 116, Wu-Kong 2nd Rd., Wu-Ku District, New Taipei City, Taiwan 24888, hereby declare that our **Besmed Guedel Airway devices (Model: AW-61112, AW-61140, AW-61150, AW-61160, AW-61170, AW-61180, AW-61190, AW-61110, AW-61111, AW-61700)** are classified as Class Is in accordance with the EU Medical Device Regulation (MDR) classification rules (Rule 5) in Annex VIII of Regulation (EU) 2017/745, and the intended users are medical personnel trained in respiratory care.

In accordance with *Regulation (EU) 2017/745, Chapter III, Section 23.1(d), "instructions for use shall be provided together with devices. By way of exception, instructions for use are not required for Class I and Class IIa devices if such devices can be used safely without any such instructions, unless otherwise specified in this Section."* Therefore, in line with this MDR exception, Instructions for Use (IFU) are not mandatory for these devices.

Besmed Health Business Corp.
CONFIDENTIAL

Sarah Lu

Sarah Lu
Vice President
11th September, 2025