GMMI
German Malaysian Medical Industries

DECLARATION OF CONFORMITY

This declaration is made in accordance with the requirements of and with the *Medical Device Directive 93/42/EC* relating to the devices stated in the attached Schedule.

Manufacturer's Name: **GMMI Sdn Bhd**

Business Address: No. 12, Persiaran Industri Rapat 2, Perindustrian Ringan Sri Rapat, 31350 Ipoh, Perak, Malaysia.
e-mail: info@gmmi-med.com

European Representative: **MDSS GmbH**
Schiffgraben 41, 30175 Hannover, Germany.

Medical Device(s): as tabled below:

No.	PRODUCT CATEGORY	MODEL VARIANTS, REF NO.	GMDN CODE
1	Tracheal Introducer	Stylet- Tracheal Tube/ Bougie Catheter, CM001 (sterile)	41829

Classification(s): **Class Is, Rule 5**

Conformity assessment route: Annex V of Directive 93/42/EEC on Medical Devices

We, the manufacturer, herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied: ISO 5361:2012 Anaesthetic and respiratory equipment – Tracheal tubes and connectors
ISO 15223-1:2016 Medical devices-Symbol to be used with medical device labels, labelling and information to be supplied-Part 1: General requirements
EN ISO 14971:2012 Medical devices -- Application of risk management to medical devices

Notified Body: Medcert GmbH
Pilatuspool 2, Hamburg 20355, Germany
NB number 0482

(EC) Certificate(s): *6646GB415190828*
Expiry Date of CE Cert: *27th May 2024*
Start of CE-Marking: *30th May 2016*
Place, Date of Issue: *Hamburg, Germany; 28th Aug 2019*

Authorised Signatory:

Signature:

Name: Dr. Frank Kubik

Position: ED

Date: 17th Sep 2019