



## EU DECLARATION OF CONFORMITY

### Manufacturer:

Jingga Anggun Sdn Bhd (1228703-A)  
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Email: [careline@empro.my](mailto:careline@empro.my)  
SRN: MY-MF-000019482

### Authorized Representative:

Pro-Tek AS, Posboks 7 Bekkelagshøgda, 1109 Oslo,  
Norway  
Email : [post@pro-tek.no](mailto:post@pro-tek.no) Tel : +47 922 37 112  
SRN: applied

We, the manufacturer, hereby declare that the medical devices covered by the present declaration, are in conformity with Medical Device Regulation (EU) 2017/745.

<b>Product Model</b>	Face Masks (Non-sterile)
<b>EMDN code and description</b>	T020604 - MEDICAL USE FACE MASKS, TYPE II AND IIR
<b>Basic UDI-DI</b>	955556610SM8786JY- MEDICAL FACE MASKS, TYPE II AND IIR
<b>Intended Use</b>	Used to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements, reduce the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.
<b>Classification and Rule</b>	Class I, Rule 1 according to Annex VIII of Regulation (EU) 2017/745
<b>Conformity Assessment Route</b>	Article 19, Annex II and Annex III according to Regulation (EU) 2017/745
<b>Standards Applicable Performance</b>	ISO 13485:2016 EN14683:2019 <b>Models</b> : SM-8786, MS31-3P, GS-319, SM-149C, VS-913, TS-8778 & MM139 meet the requirements for a type IIR medical face mask.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Signed for on behalf of **Jingga Anggun Sdn Bhd (1228703-A)**

**Name of Authorized Person:** Prof. Dr. Cocotex Yeah  
**Title:** Managing Director  
**Date:** 28/12/2022  
**Place:** Selangor, Malaysia





No.	Model Number (Ref)	EMDN Code	Product Name
1.	SM-8786 / 3 PLY AEROFIT [ S Series]	T020604	Disposable Medical Face Mask with earloop, Type IIR
2.	MS31-3P / 3 PLY AEROFIT [C SERIES]	T020604	Disposable Medical Face Mask with earloop, Type IIR
3.	GS-319 / 3 PLY AEROFIT [ G Series]	T020604	Disposable Medical Face Mask with earloop, Type IIR
4.	SM-149C / 3 PLY AEROFIT [ R Series]	T020604	Disposable Medical Face Mask with earloop, Type IIR
5.	VS-913 / 3 PLY AEROFIT [V SERIES]	T020604	Disposable Medical Face Mask with earloop, Type IIR
6.	TS-8778 / 3 PLY AEROFIT [TUX SERIES]	T020604	Disposable Medical Face Mask with earloop, Type IIR
7.	MM-139/ 3 PLY AEROFIT [M SERIES]	T020604	Disposable Medical Face Mask with earloop, Type IIR

Signed for on behalf of **Jingga Anggun Sdn Bhd (1228703-A)**




**Name of Authorized Person:** Prof Dr. Cocoalex Yeah

**Title:** Managing Director

**Date:** 28/12/2022

**Place:** Selangor, Malaysia

