



# EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC

**Document No.: DoC 113**

**Manufacturer:** Foshan United Medical Technologies Ltd.

**Address:** Southern Medical Devices Industrial Park, 89 Taoyuan East Road,  
Shishan, Nanhai, Foshan, Guangdong Province, 528225 China

**EC Representative:** Medwheat Tech Service GmbH  
Max-Planck-Straße 4 85609 Aschheim b.München Germany

**We declare under our sole responsibility that**

	Product Name	:	CMC Wound Dressing
<b>the medical device(s)</b>	Type/model, identification of product allowing traceability (Where applicable)	:	CA01E/CA01/CA01SE/CA02
<b>of class</b>	according to annex IX of directive 93/42/EEC	:	II b

**are in conformity with the provisions and requirements of directive 93/42/EEC amended by 2007/47/EC.**

Applied harmonised standards, national standards or other normative documents      Applicable harmonised standards as listed in Essential Requirements Checklist

Conformity assessment procedure      Annex II Section 3.2 of Council Directive 93/42/EEC on Medical Devices

Notified Body (name & number)      British Standards Institution (BSI)  
Notified Body Number 2797

Signed on day 13 / month 01 / of 2023.

Place Foshan city, Guangdong China

Signature Sukie Mo



Name of authorized signatory: Sukie Mo  
Position held in the company: RA Manager