


## EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: /	Hubei V-Medical Products Co., Ltd. No. 67 Xianhong Road West, Xinlirenkou, Zhanggou Town, Xiantao City, 433012 Hubei Province, P.R.China
SRN of the Manufacturer: /	CN-MF-000011268
EU Authorized Representative:/	Raffin Medical 746 route de sarcey-69490 SAINT ROMAIN DE POPEY-FRANCE
SRN:	FR-AR-000004632
Trademark:	
<b><u>As the manufacturer of the following medical device, we herewith declare under our sole responsibility that the stated medical device:</u></b>	
Name of the medical device: /	Sterile Gauze Balls
EMDN code:/	M020102
Variant configurations:/	See Appendix.
Intended purpose: /	Sterile Gauze Balls is used to cover/clean wounds or abrasions and absorb their exudates, absorb body-surface exudates. It is only intended to be used as a mechanical barrier; and not contact mucous membrane or manage the micro-environment of injured skin.
Basic UDI-DI:/	697023378stgauzeBallsZD
Applied standard	EN ISO13485:2016;EN14079:2003; EN ISO 15223-1:2021; EN ISO 20417: 2021; EN ISO 14971:2019; EN ISO 10993-1:2020; EN ISO 10993-5:2009; EN ISO 10993-10:2013; EN ISO 10993-11:2018; EN 62366-1:2015; EN ISO 11607-1:2020; EN ISO 11607-2:2020; EN ISO 11737-1:2018; EN ISO 11737-2:2020; EN ISO 11138-1:2017; EN ISO 11138-2:2017; EN ISO 14644-1:2015; EN ISO 14644-2:2015; EN ISO 10993-7:2008; EN ISO 11135: 2014; ASTM D4169:2016; ASTM F1980:2016
of class: /	Rule 4 indent 1, Class Is according to annex VIII of Regulation (EU) 2017/745 /
Conformity assessment: /	Annex XI (part A) of Regulation (EU) 2017/745 / according to Para.1 of Article 52(6) of Regulation (EU) 2017/745
Technical documentation: /	WM-ZG-10-02
Notified Body: /	TÜV Rheinland LGA Products GmbH Tillystraße 2 , 90431 Nürnberg, Germany
NB Identification number:/	CE0197
CS reference: /	None
Certificate No.: /	DZ2067318-1

Is in conformity with Regulation (EU) 2017/745 and with any other relevant Union legislation that provides for the issuing of this EU Declaration of Conformity. The declaration is valid in connection with the “final inspection report” of the device.

*For and on behalf of*  
 湖北唯美医疗用品有限公司  
 HUBEI V-MEDICAL PRODUCTS CO.,LTD.

Hubei, 2022.06.17

Place, date

Wen Guicheng, General manager.....  
*Authorized Signature(s)*  
 Name and function

Appendix

Product Name	Specifications
Gauze Balls	17 <sup>th</sup> Φ3cm、17 <sup>th</sup> Φ2.5x3cm、20 <sup>th</sup> Φ1cm、20 <sup>th</sup> Φ2.5cm、20 <sup>th</sup> Φ3cm、20 <sup>th</sup> Φ3.5cm、20 <sup>th</sup> Φ4cm、20 <sup>th</sup> Φ5.5cm