

## 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  
CN-MF-000011268

SRN of the Manufacturer: /

EU Authorized Representative:/ Raffin Medical  
746 route de sarcey-69490 SAINT ROMAIN DE  
POPEY-FRANCE

SRN: FR-AR-000004632

Trademark:



**As the manufacturer of the following medical device, we herewith declare under our sole responsibility that the stated medical device:**

Name of the medical device: / Non-woven Swabs

EMDN code:/ M020201

Variant configurations:/ See Appendix.

Intended purpose: / Non-woven Swabs 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:/ 697023378Non-WovenSwabsTH

Applied standard EN1644.1:1997; 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 11737-1:2018; EN ISO 11737-2:2020;ASTM D4169:2016

of class: / Rule 4 indent 1, Class I  
according to annex VIII of Regulation (EU)  
2017/745 /

Conformity assessment: / Annex II + Annex III of Regulation (EU) 2017/745 /  
according to Para.1 of Article 52(7) of Regulation  
(EU) 2017/745

Technical documentation: / WM-ZG-10-52

Notified Body: / None

NB Identification number:/ None

CS reference: /

None

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, 2022.12.13

Place, date

Zhang Guo Tai, General manager

Name and function

*Authorized Signature(s)*

## Appendix

No.	REF	Specifications
1	070106	Non-woven Swabs 10x10cm 4ply 30g
2	070107	Non-woven Swabs 7.5x7.5cm 4ply 40g
3	070112	Non-woven Swabs 7.5x7.5cm 4ply 40g
4	070113	Non-woven Swabs 10x10cm 4ply 40g
5	070114	Non-woven Swabs 7.5x7.5cm 4ply 40g
6	070115	Non-woven Swabs 10x10cm 4ply 40g
7	070118	Non-woven Swabs 10x10cm 4ply 40g
8	070139	Non-woven Swabs 7.5x7.5cm 4ply 40g
9	070140	Non-woven Swabs 10x10cm 4ply 40g
10	070147	Non-woven Swabs 5x5cm 4ply 40g
11	070145	Non-woven Swabs 10x20cm 4ply 40g

12	070188	Non-woven Swabs 5x5cm 4ply 30g
13	070189	Non-woven Swabs 5x5cm 4ply 40g
14	070190	Non-woven Swabs 7.5x7.5cm 4ply 30g
15	070191	Non-woven Swabs 10x10cm 4ply 30g
16	070192	Non-woven Swabs 7.5x7.5cm 4ply 40g
17	070193	Non-woven Swabs 10x10cm 4ply 40g
18	070194	Non-woven Swabs 10x10cm 4ply 40g
19	070196	Non-woven Swabs 5x5cm 4ply 30g
20	070197	Non-woven Swabs 7.5x7.5cm 4ply 30g
21	070198	Non-woven Swabs 10x10cm 4ply 30g
22	071144	Non-woven Swabs 7.5x7.5cm 4ply 30g Precounted by 5
23	071145	Non-woven Swabs 10x10cm 4ply 30g Precounted by 5
24	071147	Non-woven Swabs 7.5x7.5cm 4ply 40g Precounted by 3
25	071149	Non-woven Swabs 7.5x7.5cm 4ply 40g Precounted by 4
26	071150	Non-woven Swabs 5x5cm 4ply 30g Precounted by 5
27	071151	Non-woven Swabs 7.5x7.5cm 6ply 30g
28	071152	Non-woven Swabs 7.5x7.5cm 4ply 30g Precounted by 2
29	071153	Non-woven Swabs 7.5x7.5cm 4ply 30g Precounted by 3
30	071154	Non-woven Swabs 10x10cm 4ply 40g Precounted by 5
31	071143	Non-woven Swabs 7.5x7.5cm 4ply 40g Precounted by 5