

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:



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: / Dressing Kits

Variant configurations:/ See Appendix.

EMDN code:/ T0202

Intended purpose: / It is suitable for simple nursing in case of accidental injury of family personnel or nursing in operation in medical institutions.

Basic UDI-DI:/ 697023378DressingKitsSW

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; MEDDEV 2.7/1 REV.1;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;EN 455-1:2020 ;EN 455-2:2015; EN 455-3:2015; EN 455-4:2003

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

Conformity assessment: / Annex XI, part A

Technical documentation: / WM-ZG-10-06

Notified Body: / TÜV Rheinland LGA Products GmbH
Tillystraße 2 , 90431 Nürnberg, Germany

NB Identification number:/ CE0197

Certificate No.: / DZ2067318-1

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. /

Hubei, 2022.06.17

Place, date

For and on behalf of
湖北唯美医疗用品有限公司
HUBEI V-MEDICAL PRODUCTS CO., LTD.
Wen Guicheng, General manager
Name and function.....
Authorized Signature(s)

Appendix

No.	REF	Package contained	Packing
1	350202	1 white Tray 26,5x16,2x4,5cm	40 set/carton
2	400204	1 drape 30*48cm	56 set/carton
		8 non-woven ball 15x15cm 30g	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
3	400501	5 gauze ball 20th 20x20cm	56 set/carton
		1 Blue tweezer 12.5cm	
4	400502	5 gauze ball 20th 20x20cm	56 set/carton
		5 non-woven swab 30g 7.5x7.5cm-4ply	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
5	400508	1 drape 30*48cm	56 set/carton
		5 gauze ball 20th 20x20cm	
		5 non-woven swab 30g 7.5x7.5cm-4ply	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
6	400606	5 non-woven swab 30g 7.5x7.5cm-4ply	56 set/carton
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
7	400610	1 drape 30*48cm	56 set/carton
		5 non-woven swab 30g 7.5x7.5cm-4ply	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
8	400611	1 drape 30*48cm	56 set/carton
		5 non-woven swab 30g 7.5x7.5cm-4ply	
		5 gauze ball 20th 20x20cm	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
9	400613	1 drape 30*48cm	56 set/carton
		5 non-woven swab 30g 7.5x7.5cm-4ply	
		5 gauze ball 20th 20x20cm	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	

10	400618	5 non-woven ball 30g 15×15cm	56 set/carton
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
11	400623	1 drape 30*48cm	56 set/carton
		5 non-woven ball 30g 15×15cm	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
12	400624	1 drape 30*48cm	56 set/carton
		5 non-woven ball 30g 15×15cm	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
13	400625	1 drape 30*48cm	56 set/carton
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
14	400626	5 non-woven swab 30g 7.5×7.5cm-4ply	56 set/carton
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
15	400628	5 gauze ball 20th 20×20cm	56 set/carton
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
16	400631	1 drape 30*48cm	56 set/carton
		10 gauze swab 17th 7.5×7.5cm-8ply	
		1 Green tweezer 12.5cm	
		2 Blue Kocher's forceps 14.5cm	
17	400645	1 drape 45*45cm	56 set/carton
		8 gauze ball 20th 20×20cm	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
18	400646	1 drape 30*48cm	56 set/carton
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		5 non-woven ball 30g 15×15cm	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	

19	400651	1 drape 30*48cm	78 set/carton
		5 non-woven ball 30g 15×15cm	
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
20	400652	1 drape 30*48cm	78 set/carton
		5 non-woven ball 30g 15×15cm	
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
21	400653	5 non-woven ball 30g 15×15cm	72 set/carton
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
22	400658	1 drape 30*48cm	78 set/carton
		5 non-woven ball 30g 15×15cm	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
23	400659	6 non-woven ball 30g 15×15cm	78 set/carton
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
24	400660	5 non-woven ball 30g 15×15cm	72 set/carton
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
25	400661	5 non-woven swab 30g 7.5×7.5cm-4ply	78 set/carton
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
26	400662	1 drape 30*48cm	78 set/carton
		5 non-woven ball 30g 15×15cm	
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
27	400663	1 drape 30*48cm	78 set/carton
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	

28	400664	5 non-woven ball 30g 15×15cm	78 set/carton
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
29	400665	5 non-woven swab 30g 7.5×7.5cm-4ply	90 set/carton
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
30	400666	1 drape 30*48cm	48 set/carton
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		6 non-woven ball 30g 20×16cm	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
		1 three finger glove 22.5×50cm	
31	400667	1 drape 45*45cm	60 set/carton
		8 gauze ball 20th 20×20cm	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
32	400670-1	5 non-woven ball 30g 15×15cm	78 set/carton
		1 Green tweezer 12.5cm	
33	400671	5 non-woven swab 30g 5×5cm-4ply	90 set/carton
		1 Green tweezer 12.5cm	
34	400672	1 drape 45*45cm	78 set/carton
		5 non-woven ball 30g 15×15cm	
		1 Green tweezer 12.5cm	
35	400673	1 drape 45*45cm	78 set/carton
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		1 Green tweezer 12.5cm	
36	400676	1 drape 38*45cm	56 set/carton
		10 non-woven swab 30g 7.5×7.5cm-4ply	
		5 gauze ball 20th 20×20cm	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
37	400677	1 drape 45*45cm	80 set/carton
		8 non-woven swab 30g 7.5×7.5cm-4ply	
		8 gauze ball 20th 20×20cm	

38	400680	1 drape 38*45cm	56 set/carton
		8 non-woven ball 30g 15×15cm	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
39	400681	1 drape 38*45cm	78 set/carton
		5 gauze ball 20th 20×20cm	
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		1 red pointed tweezer 12.5cm	
		1 white pointed tweezer 12.5cm	
40	400684	10 gauze ball 20th 20×20cm	78 set/carton
		1 Blue Kocher's forceps 14.5cm	
		1 Green tweezer 12.5cm	
41	400685	1 drape 30*48cm	66 set/carton
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		8 non-woven ball 30g 15×15cm	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
		1 white towel 20×20cm	
		1 Long-sleeved white three-finger gloves 49.5×22.5cm	
42	400686	1 drape 38*45cm	56 set/carton
		5 gauze ball 20th 20×20cm	
		10 non-woven swab 30g 7.5×7.5cm-4ply	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
43	400687	1 non-woven swab 30g 7.5×7.5cm-4ply	78 set/carton
		3 gauze ball 20th 20×20cm	
		1 Blue tweezer 12.5cm	
44	400689	1 drape 38*45cm	56 set/carton
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		5 non-woven ball 30g 15×15cm	
		1 Blue Kocher's forceps 14.5cm	
		1 red pointed tweezer 12.5cm	
45	400692	1 drape 70*90cm	32 set/carton
		30 gauze swab 17th 13×13cm-16ply	

46	400700	1 drape 38*45cm	78 set/carton
		10 gauze ball 17th 15×20cm	
		1 Green tweezer 12.5cm	
		1 white pointed tweezer 12.5cm	
47	400807	1 drape 45*45cm	60 set/carton
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		12 gauze ball 20th 25×26cm	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
48	400834	1 white Tray 26,5x16,2x4,5cm	40 set/carton
		5 gauze swab 17th 10×10cm-12ply	
		1 crepe bandage 4m×10cm 75g	
		1 Knitted fabric Cloth roll 1m×7cm	
49	400836	1 drape 30*48cm	56 set/carton
		9 non-woven ball 30g 15×15cm	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
50	400858	1 drape 30*48cm	56 set/carton
		8 non-woven ball 30g 15×15cm	
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
51	400890	1 drape 30*48cm	56 set/carton
		10 non-woven swab 30g 7.5×7.5cm-4ply	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	
		1 Stainless steel scissor 12cm	
52	401010	1 drape 45*45cm	60 set/carton
		5 non-woven swab 30g 7.5×7.5cm-4ply	
		5 gauze swab 17th 7.5×7.5cm-8ply	
		10 gauze ball 20th 20×20cm	
		1 Green tweezer 12.5cm	
		1 Blue Kocher's forceps 14.5cm	

53	401045	1 drape 70*90cm	30 set/carton
		1 white Tray 32.5x17.5x4.5cm	
		10 gauze swab 17th 10x10cm-16ply	
		1 Foam stick 15cm	
		2 crepe bandage 4m×10cm 100g	
		1 Knitted fabric Cloth roll 1.5m×10cm	
54	401055-1	1 drape 50*60cm	30 set/inner carton 2 inner carton/outer carton
		1 hand towel 30x35cm	
		1 Cup 60ml	
		1 blue cup 90ml	
		1 Tray 13.7x9.5x3cm	
		5 gauze ball 17th 15x20cm	
		5 non-woven ball 30g 15x15cm	
		5 non-woven swab 30g 7.5x7.5cm-4ply	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
55	401084	1 drape 50*50cm	60 set/carton
		5 non-woven swab 30g 7.5x7.5cm-4ply	
		4 non-woven ball 30g 15x15cm	
		1 drape 45x45cm	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
		1 Non-woven face mask	
56	401084-1	1 drape 50*50cm	60 set/carton
		5 non-woven swab 30g 7.5x7.5cm-4ply	
		4 non-woven ball 30g 15x15cm	
		1 drape 45x45cm	
		1 Green tweezer 12.5cm	
		1 Blue tweezer 12.5cm	
		1 Non-woven face mask	
57	080910-1	1 Tray 24.5x13.5x4cm	35 set/carton
58	350203-1	1 Tray 32.5x17.5x4.5cm	34 set/carton
59	800116	1 Hemostatic adhesive tape 2x56cm	110 set/carton