

## 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: / Sterile Forceps

Variant configurations:/ See Appendix.

EMDN code:/ V9012

Intended purpose:/ Sterile Forceps is suitable for use in outpatient clinics or operations to clamp dressings or other device.

Basic UDI-DI:/ 697023378stforcepsWT

Applied standard:/ EN ISO13485:2016;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 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: / Class Is, Rule 1 indent 1  
according to annex VIII of Regulation (EU) 2017/745 /

Conformity assessment: / Annex XI, part A

Technical documentation: / WM-ZG-10-29

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

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Name and function *Authorized Signature(s)*

**Appendix**

No.	REF	Package contained	Packing
1	350144	Blue kocher forceps 14.5cm	70 set/carton
2	360108	Blue kocher forceps 14.5cm	70 set/carton
3	/	/	/