



# EU Declaration of Conformity

**Manufacturer:** Name: Xiamen Winner Medical Co., Ltd.  
Address: Area A, 6F, No. 588-1, TongFu Rd., 361100 TongAnt Dist., Xiamen City, Fujian Province, PEOPLE'S REPUBLIC OF CHINA  
Email: wuqing@tzmed.com

**SRN:** CN-MF-000018733

**European Representative:** Name: Shanghai International Holding Corp. GmbH (Europe)  
Address: Eiffestrasse 80, 20537 Hamburg, Germany  
Email: shholding@hotmail.com

**SRN:** DE-AR-000000001

**Product Name:** Silicon/SEBS/PVC Manual Resuscitators  
(Accessories: Masks, Positive End Expiratory Pressure Valve, Oxygen Tube, Reservoir)

**Product Type/  
Size**

	Adult	Pediatric	Infant	Neonate
Silicon	TW8111	TW8121	TW8131	TW8141
SEBS	TW8211	TW8221	TW8231	TW8241
PVC	TW8311	TW8321	TW8331	TW8341

**UMDNS Code:** 17592

Classification (MDD, Annex IX): **Ila, rule 2**  
Conformity Assessment Route: **Annex V.3**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

## DIRECTIVES

**General applicable directives:**

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

**Notified Body:** TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany

**Identification number:** CE0123

**(EC) Certificate(s):** G2 078476 0007 Rev.00

**End Date of Extension of the Validity:** 2028-12-31 [Article 120 3b, (EU) 2023/607]

**Original Expire date of the Certificate:** 2024-05-24

**Start of CE Marking:** 2020-02-20

**Place, Date of Issue:** Xiamen CHINA, 2024-05-28

**Signature:** 

**Name:** Mr. Qing Wu  
**Position:** Management Representative



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