

# EC Declaration of Conformity

We declare under our sole responsibility that

**Manufacturers Name:** Hsiner Co., Ltd.  
**Manufacturers Address:** No.312 Jhongshan Rd. Shengang Dist, Taichung City, Taiwan  
**Manufacturers SRN:** TW-MF-000007258  
**EU Representative Name** mdi Europa  
**EU Representative Address** Langenhagener Strasse71, 30855 Langenhagen, Germany  
**EU Representative SRN:** DE-AR-000006218  
**Basic UDI-DI:** 47126880500007258RPARAPU  
**Medical Group:** Respiratory Accessories for Resuscitator  
**Name of the Device (s):** Adaptor  
**Product code:** 60100-046 (E5 20140)  
**Classification:** I  
**Conformity assessment route:** according to Rule 1, and 2 in annex VIII of the Regulation MDR 2017/745

meet the below provision of the Regulation (EU) MDR 2017/745 for medical devices

Conformity assessment procedure: Regulation (EU) MDR 2017/745 annex IX, excluding section 4; the manufacturer is fully responsible for the content of declaration of conformity.

**The following Harmonized Standards are applied for all devices:**

EN ISO 20417:2021, EN ISO 14971:2019, EN ISO 10993-1:2020, EN ISO10993-5:2009,

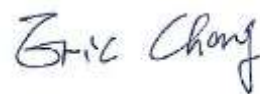
EN ISO10993-10:2013, EN ISO 13485:2016+AC:2018, EN ISO 5356-1:2015, EN ISO 15223-1:2021

**The following Non-Harmonized Standards are applied for all devices:** IEC 62366-1:2015+AMD1:2020

**The following Common Specification are applied for all devices:** N/A

Taichung, Jan. 28<sup>th</sup>, 2022

Place / Date



Eric Chang / General Manager