Hsiner Co., Ltd.
No.312 Jhongshan Rd. Shengang Dist,
Taichung City, Taiwan

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. 28th , 2022

Place / Date

Eric Chang

Eric Chang / General Manager