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
SRN (Single Registration Number):	TBD
EU Representative Name	mdi Europa
EU Representative Address	Langenhagener Strasse71, 30855 Langenhagen, Germany
Basic UDI-DI:	TBD
Medical Group:	Oropharyngeal airway, Resuscitator and Accessories (Single use), Oxygen Therapy and Accessories, Anesthesia and breathing circuit system and accessories (Single use)
Name of the Device (s):	As Attachment
Product code:	As Attachment
Classification:	I
Conformity assessment route:	according to Rule 5 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 standards are applied for all devices:
EN 1041:2008, EN ISO 14971:2019, EN ISO 10993-1:2009/AC:2010, EN ISO10993-5:2009, EN ISO10993-10:2013, EN ISO 13485:2016, EN ISO 5364:2016

Taichung, May 26, 2021
Place / Date

Ben Lin
VP of Sales and Marketing

Attachment of DoC

Medical Group	Device Name	Product Code
Oropharyngeal airway	Guedel airway	HOT01-G000-5-BOX, HOT01-G000, HOT01-G00, HOT01-G0, HOT01-G1, HOT01-G2, HOT01-G3, HOT01-G4, HOT01-G5, HOT01-G6
Resuscitator and Accessories (Single use)	Resuscitator Case	HBB05-AB
Oxygen Therapy and Accessories	Water Trap	HWF11
Anesthesia and breathing circuit system and accessories (Single use)	HOOK	HBM06-BH