

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: 47126880500007258RPAOTQR
Medical Group: Respiratory Accessories for Oxygen Therapy Devices
Name of the Device (s): Water trap
Product code: 30037, HWF11
Classification: I
Conformity assessment route: according to Rule 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 15223-1:2021, EN ISO 13485:2016+AC:2018

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 / General Manager