



Foremount Enterprise Co., Ltd.
www.foremount.com
No.17, Alley 15, Lane 5, Shenan St., Shengang Dist., Taichung
City, 42944, Taiwan (R.O.C.)
Tel: 886-4-25618788, Fax: 886-4-25618798

EC Declaration of Conformity

For the following Medical device:

Harness

(Product name)

1220101, 1220102, 1220103, 1220110, 1220112, 1220113

(Size, Model, Designation)

60882 – Headgear, disposals, soft rubber / soft silicone

(EMDN code)

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning **Medical Device Regulation (EU) MDR 2017/745** with the compliance the general safety and performance requirement – Annex I and the conformity assessment Annex VIII.

Harness is under quality management system of ISO 13485 (Certificate No.: 242282-2017-AQ-RGC-NA-PS Rev. 1.0) monitoring.

The Disposable Harness is a soft and comfortable accessory. It is used with hook ring to assist the mask putting on patient's face to supply oxygen/anesthesia gas. Disposable Harness is an accessory which made of rubber or silicone material. Both of them are Latex free. The harness with hook ring assists the mask putting on the patient's face to supply oxygen/anesthesia gas.

Classification Rule: The Disposable Harness is classified into class I of medical devices, according to Rule 1 in Annex VIII in Medical Device Regulation (EU) 2017/745, all non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies. Therefore, the Disposable Harness is classified as MDR class I device of CE classification.

SRN (Single Registration Number):

1. European Authorized Representative SRN: **MT-AR-000000234**
2. Manufacture SRN: **TW-MF-00006734**

Basic UDI-DI: 471987189D5560AM

For the evaluation regarding the Class I product safety aspects, the following harmonized standards are applied:

- The European Standard EN 1041:2008.
- International Standard EN ISO 15223-1:2016
- International Standard EN ISO 10993-1:2018.
- International Standard EN ISO 10993-5:2009.
- International Standard EN ISO 14971:2019.
- International Standard ISO 10993-10:2010.

The following European Authorized Representative is stated to the declaration:

Advena Ltd

Address: Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013 Malta.

(Company Name/Address)



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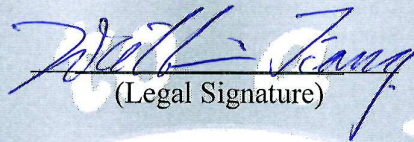
The following person is responsible for the compliance of declaration:

Foremount Enterprise Co., Ltd.

Address: No. 17, Alley 15, Lane 5, Shenan Street, Shengang District, Taichung City, Taiwan (R.O.C.)

(Manufacturer Name/Address)

William Jiang / President
(Name/Position)


(Legal Signature)

2021/05/26
(Date)

