

### **Sun-Shine Land International Ltd.**

8F, No. 69-10, Sec. 2, Chung Cheng East Road, Tamsui Dist., New Taipei City, Taiwan

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# **EC Declaration of Conformity**

Council Directive 93/42/EEC as amended by 2007/47/EC of 21 September 2007 Concerning Medical Devices.

## **Manufacturer**

Sun-Shine Land International Ltd.

8F, No. 69-10, Sec. 2, Chung Cheng E. Rd., Tamsui Dist., New Taipei City, Taiwan,

## Authorized representative in Europe

SUNGO Europe B.V.

Olympisch Stadion 24, 1076DE Amsterdam, the Netherlands

#### We declare that:

- 1. The Sun-Shine Land International Ltd. of range Items as described within Device Technical File TF. 2 version 1, conform to a Class I device of the Council Directive 93/42/EEC as amended by 2007/47/EC of 21 September 2007 concerning medical devices
- 2. Is in conformity with the provisions of that Directive and, where such is the case, with the national standards as noted within the technical file TF.2.
- 3. The requirements of Annex I, Annex VII, Annex IX have been followed for Class 1 devices and registration requirements of Article 14 have been notified to the UK Competent Authority. In support of these requirements the company follows a quality system based on ISO 9001:2015.
- 4. The declaration covers the following **Shine International Ltd.** devices placed in the market on or after JAN. 01, 2019 and until such time as a renewed conformity declaration is raised.

#### 5. Model:

HA-4266	One-Way Drinking Straws
HA-4770	Transfer Turntable
BA-7242	Bed Pan
BA-7247	Male Urinal with Lid

Issued on: 17 OCT. 2019

David Yu Authority