

Safety Notice

Medical Devices

Micro-Needling devices and Needle Cartridges



Priority 2 – Warning

HPRA Safety Notice: SN2017(23)

Issue Date: 27 June 2017

MANUFACTURER	HPRA CASE REFERENCE
Dermapenworld SUNWOO	MS30057

ISSUE

It has come to the attention of the HPRA that Micro-Needling devices manufactured by Dermapenworld and Needle Cartridges manufactured by SUNWOO are being CE marked under medical devices legislation and placed on the Irish market. The HPRA has been unable to confirm that either SUNWOO or Dermapenworld have the appropriate certification to support CE marking for these devices.

The safety, performance and quality of products which are not appropriately certified cannot be assured. The HPRA is issuing this notice to alert users, in particular cosmetic clinics, to check existing stock and contact their suppliers as necessary.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

- 1 Examine stock for Micro-Needling devices and Needle Cartridges manufactured by SUNWOO or Dermapenworld.
- 2 Take appropriate action, for example consider the need for quarantine and / or return of affected product.
- 3 Where in doubt, contact your supplier to request valid certification for your device. A valid medical device certificate should be issued by a designated Notified Body, be in date, bear the name of the device manufacturer (as named on the device labelling), and devices covered.
- 4 The HPRA would also like to emphasise that non-CE marked Micro-Needling devices should not be used for medical purposes. This includes therapeutic treatments (e.g. for disease / injury / acne) and transdermal delivery of substances to the body.

TARGET GROUPS

Cosmetic Clinics
Beauty salons

Medical aesthetic clinics
General Public

MANUFACTURER

Contact details for the manufacturers are as follows:

Dermapenworld
283 Mona Vale Road
Terrey Hills
NSW 2084
Australia

Telephone: +61 (0)2 9889 3636
E-mail: stene@equipmed.com
Website: www.dermapenworld.com

SUNWOO I&T Co.
1F, KONGKOO B/D,
371-22, SHINSOO-DONG
MAPO-GU, SEOUL,
KOREA

Telephone: +82 10-6277-7396
E-mail: sunwoo@sunwoo.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie