

# Information Notice

## Medical Devices

### Electro–Surge Limited Devices used in Electrosurgery

HPRA Information Notice: IN 2019(01)

Issue Date: 17<sup>th</sup> June 2019

#### ISSUE

It has come to the attention of the HPRA that a UK manufacturer, Electro-Surge Limited, has placed a number of devices on the European market without valid CE certification. The devices have been supplied to the Irish market by the Irish distributor KD Surgical. These devices have previously been placed on the Irish market under valid certification CE 0843, however, this CE certificate is no longer valid.

The affected devices are used in electrosurgery and are supplied in both sterile (single-use) and non-sterile (re-usable) conditions. A review of the information provided indicates that a certified sterilization facility has carried out the sterilization of the single-use sterile devices. However, this certificate does not specifically cover devices placed on the market by Electro-Surge Ltd.

Electro-Surge has issued a communication to customers requesting that they contact their distributor and place devices into quarantine.

A full list of affected devices and associated LOT numbers are listed as follows:

| Product Code | Product Description   | Lot number |
|--------------|---|------------|
| 1203-06      | Reusable Bipolar Forcep Straight, 6" (15cm) Length, 0.5mm Tip | 2827       |
| 1203-07      | Reusable Bipolar Forcep Straight 6" (15cm) Length, 1.0mm Tip  | 3220       |

|               |   |  |
|---------------|---|--|
| 1205-05       | Reusable Bipolar Bayonet Fcp, 20cm Length, 0.5mm Tip                        | 3512, 3658   |
| 1205-06       | Reusable Bipolar Bayonet Fcp,20cm Length, 1.0mm Tip                         | 3012   |
| 1701-13       | Single Use STERILE Cusco Speculum, Medium                                   | 0718011  |
| 1801-06       | Single Use 3mm Ball Electrode, PTFE Coated, 130mm Length                    | 3499   |
| 1802-05       | Single Use 5mm Ball Electrode, 130mm Length                                 | 3247   |
| 1813-03       | Single Use Loop Electrode, Green 15mm x 12mm                                | 2795   |
| 1813-04       | Single Use Loop Electrode, Yellow 10mm x 10mm                               | 2249   |
| 1813-05       | Single Use Loop Electrode, Purple 5mm x 5mm                                 | 1130   |
| 2201-01       | Single Use Bipolar McPherson Fcp,10.2cm Length, 0.5 Tip, with lead          | 3148, 3254, 3339, 3225, 3317, 3309, 3393, 3489, 3434, 3450 |
| 2201-01NSGPOT | Single Use NON-STICK McPherson Bip. Fcp.,10.2cm,0.5mm Tip, with lead        | 2535   |
| 2201-04       | Single Use Bipolar Forcep, Straight, 20cm Length, 1mm Tip, with lead        | 3376   |
| 2201-32       | Single Use Bipolar ADSON Fcp., 12cm Length, 1mm Tip, with lead              | 3143, 3372, 3628   |
| 2201-02       | Single Use Bipolar Jeweller Fcp.,11.5cm length,0.5mm Tip, with lead         | 3149, 3125, 3149, 3164, 2954                               |
| 2201-06       | Single Use Bipolar Bayonet Fcp.,22cm Length, 1mm Tip, with lead             | 3263, 3396   |
| 2201-07       | Single Use ADSON Bip. Fcp., 15cm Length,0.5mm Tip, with lead                | 3179, 3217, 3264, 3595                                     |
| 2201-10       | Single Use ADSON Bip. Fcp.,12cm Length,0.5mm Tip, with lead                 | 3079, 3059, 3129, 3343, 3438, 3424, 3539, 3580             |
| 2501-01       | Single Use ESU Pencil, push button type, with Blade electrode, 3 Mtr Length | 2816   |

Based on the information provided, at this time there is no evidence to suggest a safety risk associated with the affected devices. However, medical devices which do not hold valid CE certification may not be placed on the European market in accordance with the medical devices Directive (93/42/EEC, as amended).

## RECOMMENDATIONS

The HPRA advises that users follow the instructions provided by the manufacturer in the accompanying customer communication:

1. Refer to the accompanying customer communication and follow the instructions provided.
2. Acknowledge receipt of the customer communication to the manufacturer if you have not already done so.
3. Forward a copy of this information notice and the customer communication to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred.
4. Report any concerns regarding these devices and this issue to the manufacturer and the HPRA.
5. Consider sourcing alternative devices to ensure device shortages do not occur.

## MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Electro-Surge LTD

Unit 5, Brickfields Business Park,  
Gillingham, Dorset SP8 4PX  
Telephone: +44 (0) 1747835907  
E-mail: [sales@electrosurge.co.uk](mailto:sales@electrosurge.co.uk)

Enquiries to the **distributor** should be addressed to:

KD Surgical LTD

Tower Business Park, Loughtagalla,  
Thurles, Co. Tipperary, E41 C2p3 Ireland  
Telephone: 00353 504 34866  
E-mail: [office@kdsurgical.ie](mailto:office@kdsurgical.ie)

## HPRA CONTACT INFORMATION

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

Telephone: +353-1-6764971  
Fax: +353-1-6344033  
E-mail: [devices@hpra.ie](mailto:devices@hpra.ie)  
Website: [www.hpra.ie](http://www.hpra.ie)