



# NOTA DE SEGURIDAD EN CAMPO URGENTE – URGENT FIELD SAFETY NOTICE

<b>Manufacturer:</b>	Metsis Medikal Elektronik Ltd (Turkey)
<b>Trademark:</b>	lifePOINT
<b>Product:</b>	ADULT ELECTRODE PADS PAEDIATRIC ELECTRODE PADS <i>*Concerning those which have produced by Medeks Medikal (Turkey) for Metsis Medikal Elektronik Ltd.</i>
<b>Type of action:</b>	Withdrawal from the market. Products from the 1 <sup>st</sup> of January, 2015 to the 1 <sup>st</sup> of June 2016

## 1- IDENTIFICATION OF THE PRODUCT

The identification process is very easy due to the fact that the manufacturer Metsis Medikal Elektronik have two types of packages for their electrode pads: one of these groups is composed of white packages and they are produced by the Italian manufacturer FIAB; the other group, which is produced by the Turkish manufacturer Medeks Medikal, have silver packages. The white ones work properly and their operation is compliant. However, the silver ones are non-compliant. As it was mentioned previously, the identification is simple and the pictures below show the place where MEDEKS MEDIKAL data can be found.



**Identificación fabricante MEDEKS MEDIKAL**



## 2.- MALFUNCTION DETECTED

It has been noticed that some units of the electrode pads belonging to Metsis Medikal Elektronik Ltd trademark and produced by the Turkish manufacturer Medeks Medikal in 2015 are deteriorated, although their lifecycle is valid. The deterioration of the part which is in charge of transmitting the energy as well as the gel of the product which prevent patients from burns create a serious operational problem. Electrode pads are packaged and it is not possible for the user to verify their status without being opened. Once they are open, they must be discarded because their gel and components can lose their properties.



### 3.- RECOMMENDATIONS ON ACTIONS WHICH THE USER MUST BE TAKEN

Once users have been notified of this Urgent File Safety Notice, they must identify ADULT/PAEDIATRIC ELECTRODE PADS which are included with lifePOINT PRO/PLUS defibrillators or have been supplied as their accessories. As explained in section 1, electrode pads belonging to METSIS MEDIKAL ELEKTRONIK LTD and manufactured by MEDEKS MEDIKAL can be identified easily due to the fact that the name of this manufacturer is specified in the package.

*If your product has these electrode pads, you must put them in quarantine immediately and proceed to process their replacement by sending an email to [info@lifepoint.es](mailto:info@lifepoint.es). You must indicate the serial number of the defibrillator, the lot number of the electrode pads and your contact details, so the manufacturer proceeds to process the replacement.*

### 4.- CONTACT DETAILS

**Direct telephone number for incidences:** +34 619 121 295 (Spanish and English)

**Customer service hours:** From Monday to Thursday: 8 am – 2 pm and 4 pm – 7pm.

Fridays: 7 am – 3 pm **Email address:** [info@lifepoint.es](mailto:info@lifepoint.es)

**WEBSITE:** [www.lifepoint.es](http://www.lifepoint.es)