Registered Office: Hersegade 20 | 4000 Roskilde | Denmark
Operations Office: van der Burchstraat 40 | 2132 RN Hoofddorp | The Netherlands
Phone: +45 7033 5353 | Web: www.cardiaid.com | Mail: info@cardiaid.com

To: CardiAid distributor

Roskilde, August 9th 2019,

Ref: FSCA -19-0115

IMPORTANT SAFETY INFORMATION

Dear customer,

As part of a proactive study conducted by our supplier of Automated External Defibrillator Electrodes CA-10ES and CR-13A, we would like you to read this safety notification carefully.

It has been established that under certain circumstances, defibrillation electrodes with identical design of the electrode layer and identical riveting process, can show a partially faulty contact between the ring terminal cable and rivet, which *could result* in temporary or permanent loss of continuity.

Cardia International decided to take the following preventive corrective action:
We will replace the affected items with a corrected item

We request you to provide us with the following information within 30 days:

- Number of CardiAid AED's in your territory that carry any of the mentioned batch numbers
- Number of CardiAid AED's in your storage that carry any of the mentioned batch numbers
- Number of electrodes with mentioned batch numbers currently in storage with you, your resellers or service partners

Please send your information back to FSCA@cardiainternational.com.
This e-mail address can also be used for any other questions you might have related to this corrective action.
We will get back to you with an individual replacement plan and how to dispose of the affected items within 7 days after receiving your input.

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Please make sure that all users and other affected persons in your organization are made aware of this important safety notification. Please note that under existing legislation (Medical Device Regulation) you are obliged to comply with the requirements of this corrective action.

Annotation: Electrodes on the market with the same MODEL number but with different lot numbers than those listed in this letter, are not affected and can be used without restrictions.

We apologize for any inconveniences that this may cause. Our utmost concern and top priority is to ensure that our customers can use our products safely and that patients are given any necessary treatment without delay. For exactly this purpose, it is absolutely essential to carry out the described corrective measures without delay.

Kind regards,

Balu Ganapathy
Head of Regulatory and Quality Management
email: FSCA@cardiainternational.com

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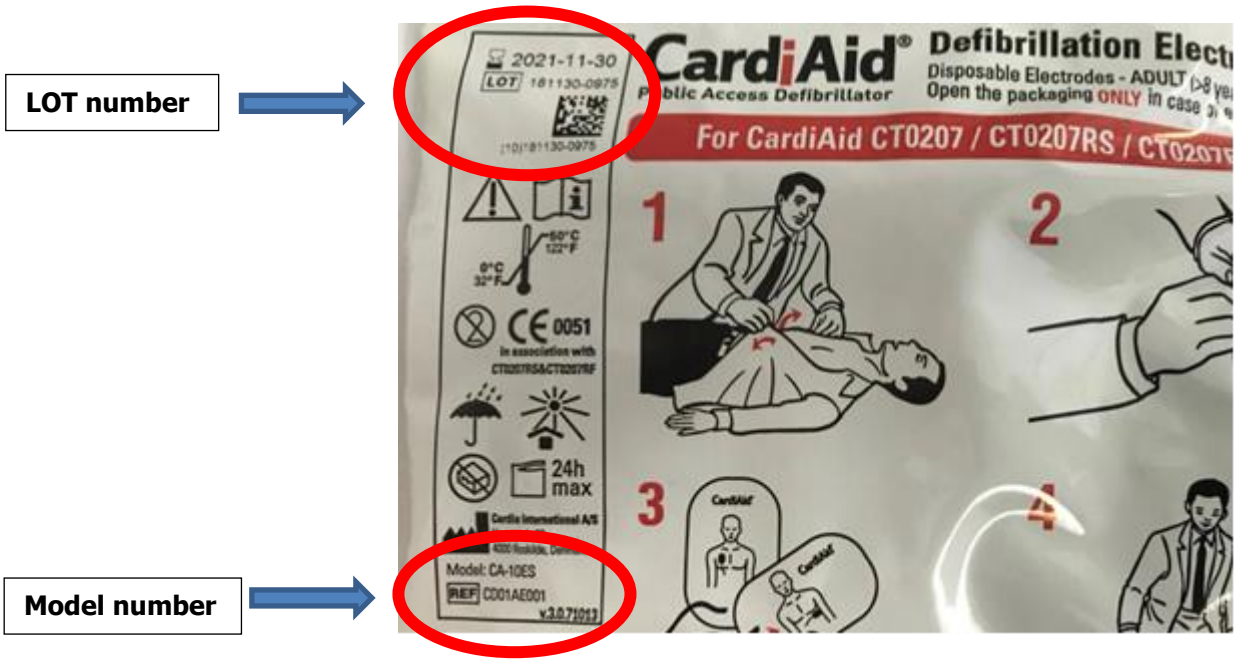
ANNEX 1

The following LOT numbers for **CardiAid Electrode CA-10ES** are affected:

LOT number:	**Expiry date:**
60722-0975	2019-07
60928-0973	2019-09
161118-0972	2019-11
61219-0979	2019-12
70111-0972	2020-01
70426-0971	2020-04
70720-0974	2020-07
70829-0978	2020-08
71222-0976	2020-12
180403-0974	2021-04
180828-0979	2021-08
181130-0975	2021-11

Identification of the LOT numbers on the Product Packaging:

The lot number is printed on each pouch and market with LOT. Below it is highlighted in red as an example. The MODEL number of the electrode is also highlighted in red.



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The following LOT numbers for **CardiAid Electrode CR-13A** are affected:

LOT number:	**Expiry date:**
180702-0972	2021-07

Identification of the LOT numbers on the Product Packaging:

The lot number is printed on each pouch and market with LOT. Below it is highlighted in red as an example. The MODEL number of the electrode is also highlighted in red.

LOT number

Model