Importer:
Sharkmed Oy
Martinsyrjäntie 8 A3,
05810 Hyvinkää, Finland
Tel: +358 19 414 581
asiakaspalvelu@sharkmed.fi

Date: 21. December 2021
Revision: 1
Importer's reference number: SM-172

Urgent Field Safety Notice

Credo Cube 4l
Credo paneelisetti (6 kpl), Credo set of six TIC panels

Procedure: product recall

For attention of: all users of the device

Contact details of importer (name, e-mail, telephone, address etc.)
Sharkmed Oy Martinsyrjäntie 8 A3, 05810 Hyvinkää, Finland asiakaspalvelu@sharkmed.fi +358 19 414 581 www.sharkmed.fi Contact person: Osmi Kiiski Quality Manager +358 44 231 0489 osmi.kiiski@sharkmed.fi

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1. Information of Affected Devices

Device type:

Temperature-controlled transport container for transporting for example medicines and blood

Manufacturer's description:

Crēdo Cube™ passive, reusable shippers protect your payload and the environment. Keep your most valuable medical materials at just the right temperature for up to five days while reducing your carbon footprint and decreasing costs.

Commercial name(s):

Credo Cube 4l
Credo paneelisetti (6 kpl), Credo set of six TIC panels

Primary clinical purpose of device(s):

The manufacturer has not defined the product as a medical device.

Device number / product code:

Credo Cube 4l, product code: S4 4 96 CUBE
Credo paneelisetti (6 kpl), product code: CR04ATICSYS4

2. Reason for Field Safety Corrective Action (FSCA)

Description of the product problem:

The product is not in compliance with EU regulation.

Hazard giving rise to the FSCA:

The safety and performance of the product have not been demonstrated in accordance with EU legislation. The product does not have the required CE marking for medical device. There is a risk that the temperature of the product transported in the container cube will not remain at the correct level.

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3. Type of Action to mitigate the risk

Action To Be Taken by the User:

☒ Identify Device
☒ Quarantine Device
☒ Return Device

By when should the action be completed?

The product must be taken out of use immediately and returned no later than 14 January 2022.

Is customer reply required?

Yes. Please return the customer reply form attached in email as soon as possible, but not later than January 14, 2022 to: asiakaspalvelu@sharkmed.fi

4. General information

FSN Type:

new.

Manufacturer information:
(Importer information is in the beginning of this notice)

Name: PELI BIOTHERMAL
Address: Stanbridge Buildings, Celsius House, Stanbridge, Rd, Leighton Buzzard LU7 4QQ, United Kingdom
Website address: https://pelibiothermal.com/

National Competent Regulatory Authority has been informed about this communication to customers.

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Transmission of this Field Safety Notice

This notice needs to be passed on all those who use the Credo Cube 4 and its Credo set of six TIC panels and to all who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the importer, manufacturer and the national Competent Authority.