

2.Apr.2021

Notification Letter

Dear sir or madam,

Product Name : Sterilized Drape for PDE

Reference No.0823802



This product is a sterilized, disposable cover made exclusively for the "Infrared Observation Camera System (Product Name: Photodynamic Eye PDE and pde-neoII)" manufactured by Hamamatsu Photonics. Gamma ray sterilization ($SAL = 10^{-3}$) has been performed in the manufacturing process since the product first went on sale. According to ISO11137-1: 2006, the international standard for radiation sterilization validation, sterility assurance level $SAL = 10^{-3}$ is recognized for sterilization of medical devices. Sterility assurance level $SAL = 10^{-3}$ is even in compliance with US national standard ANSI / AAMI ST67: 2019 for drapes that do not come into contact with the living body. We therefore determined that sterility assurance level $SAL = 10^{-3}$ is adequate for the latest equipment.

We applied for CE mark certification in 2008. The submission document relating to gamma ray sterilization validation of drapes set at $SAL = 10^{-3}$ was reviewed by the notified body who concluded it was adequate. As a result, the device was certified by the notified body on May 22nd, 2008 (Certificate number CE77715), since then the product was CE marked with the number of the Notified Body (2797). Although the document related to sterilization has been reviewed by notified body periodically, nothing of significance was subsequently pointed out. It was therefore determined that sterilization conditions and labeling were adequate.

European sterilization labelling standard EN556-1: 2001 however requires sterility assurance level $SAL = 10^{-6}$ when "STERILE" is displayed on the labelling of CE products and the notified body pointed out that this product did not meet the requirements at the latest audit.

As a corrective action for this labeling non-conformity, "STERILE" will be removed from the product labeling. Also, we will revoke the CE certification as a sterile product and re-label the product as a normal class I device. Notified body number 「2797」 will also be removed from the labeling.

There have been no reports of sterilization defects or infectious diseases caused by the product in Europe and Japan. Sterility assurance level of drape SAL = 10^{-3} is even in compliance with US national standard ANSI / AAMI ST67: 2019. Based on these facts, this product will continue to undergo gamma ray sterilization at the sterility assurance level SAL = 10^{-3} with no effect on the safety of this product.

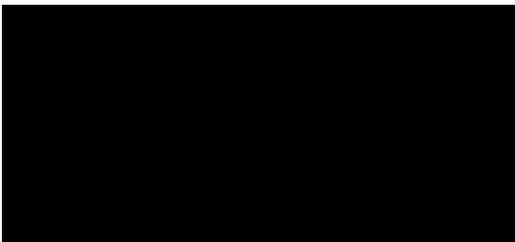
For the products which will be shipped in the future, the word "STERILE" will be removed from the label and IFU. Although "STERILE" will be removed from the labelling, this drape can continue to be used clinically as a sterilized disposable.

Distributor:

HAMAMATSU PHOTONICS K.K.

Manufacturer:

Fuji Systems Corporation



Rev 1: September 2018

FSN Ref: FSN-2021-01

FSCA Ref: FSCA-2021-01

Date: 02.04.2021

Urgent Field Safety Notice
Sterilized Drape for PDE

For Attention of*:User

Contact details of local representative (name, e-mail, telephone, address etc.)*

Hamamatsu Photonics Deutschland GmbH
Arzbergerstrasse 10 D-82211 Herrsching Germany
Tel:+49-8152-375-203 Fax: +49-8152-375-222

Urgent Field Safety Notice (FSN)
Sterilized Drape for PDE
Risk addressed by FSN

| 1. Information on Affected Devices* | |
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| 1 . | <p>1. Device Type(s)*</p> <p>This product is a sterilized, disposable cover made exclusively for the "Infrared Observation Camera System (Product Name: Photodynamic Eye PDE and pde-neoII) " manufactured by Hamamatsu Photonics.</p> <div style="display: flex; justify-content: space-around;">   </div> |
| 1 . | <p>2. Commercial name(s)</p> <p>Sterile Drape for PDE</p> |
| 1 . | <p>3. Unique Device Identifier(s) (UDI-DI)</p> <p>4544050088459</p> |
| 1 . | <p>4. Primary clinical purpose of device(s)*</p> <p>This product is used to prevent contamination of the human body or camera.</p> |
| 1 . | <p>5. Device Model/Catalogue/part number(s)*</p> <p>0823802</p> |
| 1 . | <p>6. Software version</p> <p>N/A</p> |
| 1 . | <p>7. Affected serial or lot number range</p> <p>ALL LOT numbers</p> |
| 1 . | <p>8. Associated devices</p> <p>N/A</p> |

| 2 Reason for Field Safety Corrective Action (FSCA)* | |
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| 2 | <p style="text-align: center;">1. Description of the product problem*</p> <ul style="list-style-type: none"> · "STERILE" is included in the CE product label, but the notified body pointed out that it does not meet the "STERILE" label requirement ($SAL \leq 10^{-6}$) of EN 556-1: 2001. |
| 2 | <p style="text-align: center;">2. Hazard giving rise to the FSCA*</p> <ul style="list-style-type: none"> · There have been no reports of sterilization defects or infectious diseases caused by the product in Europe and Japan. Sterility assurance level of drape $SAL = 10^{-3}$ is even in compliance with US national standard ANSI / AAMI ST67: 2019. Based on these facts, this product will continue to undergo gamma ray sterilization at the sterility assurance level $SAL = 10^{-3}$ with no effect on the safety of this product. For the products which will be shipped in the future, the word "STERILE" will be removed from the label and IFU. Although "STERILE" will be removed from the labelling, this drape can continue to be used clinically as a sterilized disposable. |
| 2 | <p style="text-align: center;">3. Probability of problem arising</p> <ul style="list-style-type: none"> · Not applicable |
| 2 | <p style="text-align: center;">4. Predicted risk to patient/users</p> <ul style="list-style-type: none"> · There is no new risk to patient and users. |
| 2 | <p style="text-align: center;">5. Further information to help characterise the problem</p> <ul style="list-style-type: none"> · Sterility assurance level of drape $SAL = 10^{-3}$ even complies with the US national standard ANSI / AAMI ST67: 2019. The product will therefore continue to be sterilized with gamma-rays at the sterility assurance level $SAL = 10^{-3}$. |
| 2 | <p style="text-align: center;">6. Background on Issue</p> <ul style="list-style-type: none"> · This product is a sterilized, disposable cover made exclusively for the "Infrared Observation Camera System (Product Name: Photodynamic Eye PDE and pde-neoII) " manufactured by Hamamatsu Photonics. Gamma ray sterilization ($SAL = 10^{-3}$) has been performed in the manufacturing process since it first went on sale. According to ISO11137-1: 2006, the international standard for radiation sterilization validation, sterility assurance level $SAL = 10^{-3}$ is recognized for sterilization of medical devices. Sterility assurance level $SAL = 10^{-3}$ is even in compliance with US national standard ANSI / AAMI ST67: 2019 for drapes that do not come into contact with the living body. We therefore determined that sterility assurance level $SAL = 10^{-3}$ is adequate for the latest equipment. European sterilization labelling standard EN556-1: 2001 however requires sterility assurance level $SAL = 10^{-6}$ when "STERILE" is displayed on the labelling of CE products and the notified body pointed out that this product did not meet the requirements at the latest audit. |
| 2 | <p style="text-align: center;">7. Other information relevant to FSCA</p> <ul style="list-style-type: none"> · As a corrective action, we will remove "STERILE" on the product label and IFU and change the label to indicate that gamma ray irradiation is performed at the sterility assurance |

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| | level (SAL = 10^{-3}). In addition, we will cancel the CE certificate specializing in sterilization and re-submit as a normal class I. We will stop shipping to Europe until the label and IFU are revised. For already distributed products on the EU market, we distribute this FSN and notification letter that explains the background and our corrective action to users. |
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| 3. Type of Action to mitigate the risk* | | | | | | | |
|---|---|---|------------------|---|--|----|--|
| 3. | <p>1. Action To Be Taken by the User*</p> <p> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None </p> | | | | | | |
| 3. | <table border="1" style="width: 100%;"> <tr> <td style="width: 35%;">2. By when should the action be completed?</td> <td>End of May,2021</td> </tr> </table> | 2. By when should the action be completed? | End of May,2021 | | | | |
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| 3. | <table border="1" style="width: 100%;"> <tr> <td style="width: 45%;">3. Particular considerations for:</td> <td>N/A</td> </tr> <tr> <td colspan="2">Is follow-up of patients or review of patients' previous results recommended?</td> </tr> <tr> <td colspan="2">No</td> </tr> </table> | 3. Particular considerations for: | N/A | Is follow-up of patients or review of patients' previous results recommended? | | No | |
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| No | | | | | | | |
| 3. | <table border="1" style="width: 100%;"> <tr> <td style="width: 65%;">4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</td> <td>No</td> </tr> </table> | 4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) | No | | | | |
| 4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) | No | | | | | | |
| 3. | <p>5. Action Being Taken by the Manufacturer</p> <p> <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None </p> | | | | | | |
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| 3. | <table border="1" style="width: 100%;"> <tr> <td style="width: 65%;">7. Is the FSN required to be communicated to the patient /lay user?</td> <td>No</td> </tr> </table> | 7. Is the FSN required to be communicated to the patient /lay user? | No | | | | |
| 7. Is the FSN required to be communicated to the patient /lay user? | No | | | | | | |
| 3 | <table border="1" style="width: 100%;"> <tr> <td colspan="2">8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?</td> </tr> <tr> <td colspan="2">No</td> </tr> </table> | 8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? | | No | | | |
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| No | | | | | | | |

| 4. General Information* | |
|--------------------------------|---|
| 4. | 1. FSN Type* New |
| 4. | 2. For updated FSN, reference number and date of previous FSN N/A |
| 4. | 3. For Updated FSN, key new information as follows: N/A |
| 4. | 4. Further advice or information already expected in follow-up FSN? * No |
| 4 | 5. If follow-up FSN expected, what is the further advice expected to relate to: N/A |
| 4 | 6. Anticipated timescale for follow-up FSN N/A |
| 4. | 7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN) |
| | a. Company Name Fuji Systems Corporation, Shirakawa Plant |
| | b. Address 200-2 Aza-Ohira, Odakura, Nishigo, Nishi Shirakawa Gun, Fukushima 961-8061 JAPAN |
| | c. Website address http://www.fujisys.co.jp/en/index.html |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * No |
| 4. | 9. List of attachments/appendices: |
| 4. | 10. Name/Signature |

| Transmission of this Field Safety Notice | |
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| | <p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*</p> |

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.