# Urgent Field Safety Notice
# “Sterile Hydrophilic Gel for endoprothetics of human soft tissues Los Deline®”

For Attention of*: Distributors of “Sterile Hydrophilic Gel for endoprothetics of human soft tissues Los Deline®”

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
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| This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages |

# Urgent Field Safety Notice (FSN)
# "Sterile Hydrophilic Gel for endoprothetics of human soft tissues Los Deline®"

The manufacturer BIOTRH s.r.o. decided to voluntarily withdraw any remaining supply of the medical device Los Deline 100g in European markets.

| 1. **Information on Affected Devices*** | |
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| 1. | 1. Device Type(s)* |
| | Sterile Hydrophilic Gel for endoprothetics of human soft tissues Los Deline® is an injectable soft tissue filler intended to be used for the correction of soft tissue defects. |
| 1. | 2. Commercial name(s) |
| | Sterile Hydrophilic Gel for endoprothetics of human soft tissues Los Deline® |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | N/A |
| 1. | 4. Primary clinical purpose of device(s)* |
| | Sterile Hydrophilic Gel for endoprothetics of human soft tissues Los Deline® is intended to be used for the correction of soft tissue defects. It is currently indicated for usage for endoprosthetics of soft tissues of breast, buttocks and trunk area. It achieves its intended purpose to improve or restore volume of soft tissues by expanding the tissue through the space occupying effect of the filler material |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | Los Deline® 100g in containers |
| 1. | 6. Software version |
| | N/A |
| 1. | 7. Affected serial or lot number range |
| | B012021, B032021, B042021, B052021, B062021, B082021, B102021, B112021, B122021, B132021, B142021, B152021, B162021, B182021, B192021, B202021, B212021, B222021, B232021, B242021, B252021, B262021, B282021, B292021, B352021, B372021, B412021, B422021, B492021, B502021, B522021, B532021, B552021, B012022, B022022, B052022, B132022, B142022, B152022, B172022, B312022, B522022, B592022, B602022, B622022, B732022, B822022 |
| 1. | 8. Associated devices |
| | N/A |

| 2 **Reason for Field Safety Corrective Action (FSCA)*** | |
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| 2. | 1. Description of the product problem* |
| | Suspension and termination of the CE Certificates by Notified Body |
| 2. | 2. Hazard giving rise to the FSCA* |
| | No immediate risk for the health of patients having the affected device has been identified |
| 2. | 3. Probability of problem arising |
| | This is considered a precautionary activity. |
| 2. | 4. Predicted risk to patient/users |
| | At this stage no immediate risk for the health of patients having the affected device has been identified. |
| 2. | 5. Further information to help characterise the problem |
| | N/A |
| 2. | 6. Background on Issue |

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| | Based on a call for corrective action sent on 20.06.2023 by the State Institute for Drug Control, (SUKL), company BIOTRH s.r.o. decided to voluntarily withdraw any remaining supply of the medical device Los Deline 100g in European markets.<br>The call was sent because, according to SUKL, the medical device Los Deline poses an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of public health protection.<br>No substantiated scientific evidence of the specific risks of the product has been provided by SUKL to BIOTRH s.r.o.<br>This is considered a precautionary activity conducted as requested by SUKL. The SUKL recommendation, and this action, is not based on new scientific evidence regarding our product.<br>The remaining products (Medical device Los Deline 100g bag) will be recalled. Due to the 3-year expiry date of the product, according to sales records, product leftovers may be in the following countries: Sweden, Germany, Italy, Greece, Turkey, Switzerland, Cyprus, France, Norway.<br>The manufacturer has not sold the product to the European market since the date of suspension of certificates (23.03.2023), according to the requirements of Notified Body.<br>Our product has been CE marked since 2018. From the moment the certificate was obtained, the manufacturer had promptly corrected all nonconformities that were discovered by the Notified Body during regular audits.<br>The safety profile of BIOTRH s.r.o. product is supported by pre-clinical, clinical, and post -marketing data. The manufacturer will continue to conduct studies that could confirm the safety of the product.<br>On 23.03.2023 the manufacturer was informed by the by Notified Body, SZUTEST Uygunluk Değerlendirme A.Ş., NB 2195 about the suspension of the CE certificate was due to the unsatisfactory results of an intracutaneous reactivity test (On samples taken during the unannounced audit).<br>The Notified body SZUTEST Uygunluk Değerlendirme A.Ş., NB 2195 requested the manufacturer to recall the affected batch from the market. Batch B132022 was withdrawn from the market of the Republic of Turkey where it was distributed, in accordance with the requirements of the Notified Body (FSCA-23-001-TR).<br>For a continuous period of time and despite numerous requests and reminders SZUTEST did not provide BIOTRH with the test protocols by which it grounded suspension of BIOTRH's certificates. Based on the agreement with the Notified Body during the audit in January 2023, the company Biotrh s.r.o. agreed to conduct a study according to ISO 10993-23- Intracutaneous (Intradermal) Reactivity on samples sealed by Notified body during previous announcement audit. The results of the "Test for intracutaneous reactivity according to ISO 10993-23: Intracutaneous (Intradermal) Reactivity Test in Albino Rabbits" confirmed safety of the product under evaluation.<br>The manufacturer also ordered Intracutaneous (Intradermal) Reactivity test on the retention samples of affected batch (B132022). The company Biotrh s.r.o. currently already has test results on the retention samples of affected batch, where the absence of skin irritation potential was indicated according to the requirements of the intracutaneous reactivity test ISO 10993-23. The results of the test performed by Notified Body raise reasonable suspicions since it was conducted in a non-certified laboratory and the ISO requirements for this test were not met.<br>After Notified body received results of Intracutaneous (Intradermal) Reactivity test on samples sealed by Notified body during previous announcement audit, the Notified Body sent to manufacturer an email dated 02.05.2023 with the decision regarding withdrawal of BIOTRH's certificates. Pursuant to the Decision the following grounds for the withdrawal of certificates were stated:<br>(a) the outcomes of the published literature and reported medical incidents demonstrate the side effects and complications are not acceptable when weighed against the intended safety and performance of the product, |

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| | (b) the reported risks associated with using the device are incompatible with a high level of protection of health and safety,<br>(c) the product cannot be considered as an acceptable treatment option for its intended purpose in term of state of art.<br>The above referred reasons were summarised as the "evolvement of science and treatment alternatives" and "state of the art is an evolving concept".<br>The manufacturer consider that the stated grounds for certificates withdrawal are far-fetched and not based on objective and scientific evidence. The Notified Body stated withdrawal grounds and continuous change of position and reasoning throughout the process of unannounced audit show not only the lack of objectivity and scientific approach, but also the lack of impartiality and independency in taking the decisions.<br>Since the suspension and termination of certificates, in our opinion, is unproven, the manufacturer filed an appeal against this decision and will defend its case. |
| 2. | 7. Other information relevant to FSCA |
| | N/A |

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| | **3. Type of Action to mitigate the risk*** | |
| **3.** | **1. Action To Be Taken by the User*** | |
| | ☐ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device<br>☐ On-site device modification/inspection<br>☐ Follow patient management recommendations<br>☐ Take note of amendment/reinforcement of Instructions For Use (IFU)<br>☐ Other ☐ None<br>As a precautionary measure, we request that you immediately hold remaining "Sterile Hydrophilic Gel for endoprothetics of human soft tissues Los Deline®" (Batch numbers B012021, B032021, B042021, B052021, B062021, B082021, B102021, B112021, B122021, B132021, B142021, B152021, B162021, B182021, B192021, B202021, B212021, B222021, B232021, B242021, B252021, B262021, B282021, B292021, B352021, B372021, B412021, B422021, B492021, B502021, B522021, B532021, B552021, B012022, B022022, B052022, B132022, B142022, B152022, B172022, B312022, B522022, B592022, B602022, B622022, B732022, B822022) you have on hand in your facility, and we will contact you soon to organize the return of these products. | |
| 3. | 2. By when should the action be completed? | Immediately |
| 3. | 3. Particular considerations for: Implantable device<br>Is follow-up of patients or review of patients' previous results recommended?<br>No<br>Routine check-up will healthcare provider is recommended. No immediate risk for the health of patient having the affected device has been identified. Please inform your customers to follow patients per standard postoperative protocol, continue to monitor adverse events and, if it occurs, manage per normal standard of care. | |
| 3. | 4. Is customer Reply Required? * | Yes |

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| | (If yes, form attached specifying deadline for return) | (deadline for return 30.07.2023) |
| **3.** | **5. Action Being Taken by the Manufacturer**<br><br>☒ Product Removal ☐ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☐ Other ☐ None<br><br>No action with regards to already implanted devices | |
| 3 | 6. By when should the action be completed? | Immediately |
| 3. | 7. Is the FSN required to be communicated to the patient /lay user? | No |

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| | **4. General Information*** | |
| 4. | 1. FSN Type* | New |
| 4. | 2. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | **Biotrh s.r.o.** |
| | b. Address | **Lyčkovo náměstí 508/7186 00 Prague 8, Czech Republic** |
| | c. Website address | **www.losdeline.com** |
| 4. | 3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * | |
| 4. | 4. Name/Signature | **Lukáš Šlechta**<br><br>Lukáš Šlechta Digitálně podepsal Lukáš Šlechta Datum: 2023.07.10 08:34:23 +02'00' |

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| | **Transmission of this Field Safety Notice** |
| | 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)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>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.* |