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 the medical device Los Deline 100g from EU and EEA markets.

1. **Information on Affected Devices***	
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)***	
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
	Based on a call for corrective action sent on 20.06.2023 by the Czech State Institute for Drug Control, (SUKL), company BIOTRH s.r.o. decided to voluntarily withdraw the medical

	device Los Deline 100g from EU market, due to suspension and termination of the CE Certificates by Notified Body. The remaining products (Medical device Los Deline 100g bag) will be recalled in the EU and EEA countries where it was distributed. The safety profile of BIOTRH s.r.o. product is supported by pre-clinical, clinical, and post -marketing data. No substantiated scientific evidence of the specific risks of the product has been provided to manufacturer from Notified Body and has not discovered during risk analysis. The reasons for the certificate termination were summarised as the "evolvement of science and treatment alternatives" and "state of the art is an evolving concept". The manufacturer will continue to conduct studies confirming that the product can be used as an alternative method to shell implants.
2.	7. Other information relevant to FSCA
	N/A

	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 ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None 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 Is follow-up of patients or review of patients' previous results recommended? No 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

	(If yes, form attached specifying deadline for return)	(deadline for return 25.08.2023)
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None 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

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Manufacturer information	
	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	[redacted]

	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) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) 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 manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*