Skulle Implants Oy	Field Safety Notice (FSN) 22001

Urgent Field Safety Notice

Date: January 28, 2022

Commercial name: **GLACE™** Custom Made CMF Implant

Type of action: Advisory Notice

Dear Sir/Madam,

Skulle Implants Oy issues this Urgent Field Safety Notice (FSN) to inform healthcare providers in [name of country] of the following information.

Description of the Issue

Skulle Implants Oy has unintentionally misinterpreted the transitional provisions of the MDR (Article 120). The conformity of GLACE™ Custom Made CMF Implant has not been assessed by a designated notified body. According to recently updated European regulation, the conformity assessment by the manufacturer of custom-made implants in risk class III need to be supported by an EC certificate issued by a designated notified body.

Therefore, we are obliged to inform that GLACE™ Custom Made Implants are currently non-compliant with the current regulation.

Skulle Implants Oy has initiated a conformity assessment with a designated notified body to gain back the compliance as soon as possible. Meanwhile, GLACE™ implants may only be used for individual patients with exempt permission from local authority. Skulle Implants is currently working on exempt permission with your local competent authority.

Affected Products

Product name	Product Code	Lot
GLACE™ Custom Made CMF Implant	SIC-1000	All products delivered after 26.5.2021

Clinical Impact

There are no patient safety issues related to GLACE™ implant. The device has remained the same in transition from MDD to MDR. No changes to implant itself, its composition, components, or manufacturing are made since its launch in 2014. As of today, over 2000 implants are sold and implanted with appraising feedback from clinicians. According to our clinical advisors, the missing certificate as such does not create any need for re-operation of the patients who have received the custom-made GLACE™ implant after May 26, 2021.

Recommended User Action

- Do not implant GLACE™ Custom Made CMF Implant until a further notice from Skulle Implants. Until renewed market clearance, GLACE™ implants can only be used with a special permission from local competent authority.
- Forward this notice to anyone in your facility that needs to be informed
- Forward this notice to all the hospitals who have received GLACE™ implant after May 26, 2021
- Advise the hospital to add in applicable patient records that GLACE™ implant has not been in compliance with the current regulation (MDR 2017/745) since May 26, 2021
- Ensure that your customers have received and understood the information of this notification
- Keep records of informed and responded customers
- Review, complete, sign and return the attached Confirmation Form accompanying this notification in accordance with the directions on the form

The local competent authority [name of local authority] has been notified of this action. This notice has been drafted in consultation with the appropriate regulatory authorities.

Further information and support

Direct any additional manufacturer inquiries to orders@skulleimplants.com

and to

hanna.nikkila@skulleimplants.com

Hanna Nikkilä
Sales Director
+358 400 27 99 96

Confirmation of receipt of communication

(Advisory Notice dated Jan 28, 2022)

GLACE™ Custom Made CMF Implant

Product code: SIC-1000

Lot number: All products delivered after May 26, 2021

Please complete and return copy of this form by email to orders@skulleimplants.com as confirmation that you have received this notification.

Company/Hospital Name:	
This confirmation is completed by:	
Title:	
Email address:	
Telephone number:	
Signature/Date:	

We have received the above-mentioned letter, performed the actions outlined in the letter, and have disseminated the information / documentation to our staff, customers, hospitals, and any other stakeholders, as applicable.