

10<sup>th</sup> October 2023

**URGENT - Field Safety Notice**

To all users of the BIO-AQUACEL EYE SAFE

**Re: Bio-Aquacel Eye Safe with Contamination Problem**

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using Bio-Aquacel Eye Safe manufactured and distributed from Year 2019 to current date, August 2023 which are the following batch ;

Product Number/ Catalogue Number	Lot/Serial Number	Manufacturing/ Distribution Date	Expiration Date
FFP032.010	19KL0012	08/2019	08/2021
FFP032.010	19KL0015	08/2019	08/2021
FFP032.010	19KL0016	08/2019	08/2021
FFP032.010	20EL0050	05/2020	05/2022
FFP032.010	20EL0058	05/2020	05/2022
FFP032.010	20EL0060	06/2020	06/2022
FFP032.010	20FL0064A	06/2020	06/2022
FFP032.010	20FL0064B	06/2020	06/2022
FFP032.010	20FL0064C	06/2020	06/2022
FFP032.010	20FL0064D	06/2020	06/2022
FFP032.010	20JL0066A	07/2020	07/2022
FFP032.010	20JL0066B	07/2020	07/2022
FFP032.010	20KL0077A	08/2020	08/2022
FFP032.010	20KL0077B	08/2020	08/2022
FFP032.010	20NL0093A	10/2020	10/2022
FFP032.010	20NL0093B	10/2020	10/2022
FFP032.010	20NL0093C	10/2020	10/2022
FFP032.010	20QL0102A1	12/2020	12/2022
FFP032.010	20QL0102A2	12/2020	12/2022
FFP032.010	20QL0102B	12/2020	12/2022
FFP032.010	21AL0003A	01/2021	01/2023
FFP032.010	21AL0003B	01/2021	01/2023
FFP032.010	21AL0003C	01/2021	01/2023
FFP032.010	21AL0003D	01/2021	01/2023
FFP032.010	21DL0035A	04/2021	04/2023
FFP032.010	21DL0035B	04/2021	04/2023
FFP032.010	21DL0035C	04/2021	04/2023
FFP032.010	21DL0035D	04/2021	04/2023
FFP032.010	21JL0062A	07/2021	07/2023
FFP032.010	21JL0062B	07/2021	07/2023
FFP032.010	21JL0062C	07/2021	07/2023
FFP032.010	21JL0062D	07/2021	07/2023
FFP032.010	21JL0062E	07/2021	07/2023



FFP032.010	21ML0082A	09/2021	09/2023
FFP032.010	21ML0082B	09/2021	09/2023
FFP032.010	21ML0082C	09/2021	09/2023
FFP032.010	21QL0105A	12/2021	12/2023
FFP032.010	21QL0105B	12/2021	12/2023
FFP032.010	21QL0105C	12/2021	12/2023
FFP032.010	22CL0022A	03/2022	03/2024
FFP032.010	22CL0022B	03/2022	03/2024
FFP032.010	22CL0022C	03/2022	03/2024
FFP032.010	22FL0040	06/2022	06/2024
FFP032.010	22FL0041	06/2022	06/2024
FFP032.010	22KL0051A	08/2022	08/2024
FFP032.010	22KL0051B	08/2022	08/2024
FFP032.010	22KL0051C	08/2022	08/2024
FFP032.010	22KL0051D	08/2022	08/2024
FFP032.010	22NL0071A	10/2022	10/2024
FFP032.010	22NL0071B	10/2022	10/2024
FFP032.010	22NL0071C	10/2022	10/2024
FFP032.010	23FL0034A	06/2023	06/2025
FFP032.010	23FL0034B	06/2023	06/2025

#### When does this malfunction occur and what are the potential risks ?

Malfunction of the medical device is due to **Contamination Problem – Code A18**. This problem associates with the presence of any unexpected foreign substance found in the device, which may affect performance or intended use of the device. On 24<sup>th</sup> August 2023, Medical Device Authority (MDA) sent a notification to Farmasia Sdn. Bhd. and stated that Bio-AQUACEL Eye Safe have been confirmed to have contamination from an undeclared ingredient as per registered and approved by the authority. This raise concerns and safety issues as our finished product quality has been compromised without our knowledge.

The effects of the undeclared ingredient in Bio-AQUACEL Eye Safe however has not yet been studied and could possibly cause temporary or reversible health consequences; or there is remote probability that the device will cause serious consequences. Nevertheless, to current date, Bio-AQUACEL Eye Safe has not received any complaints and has no reported adverse event associated to this issue.

#### What steps can the user take to avoid the potential risk of this issue?

- Immediate stop and discontinuance of the Bio-Aquacel Eye Safe usage.
- Return the remaining stock of Bio-Aquacel Eye Safe to the Manufacturer.
- Seek medical attention if any adverse reaction is observed.

#### How will the issue finally be resolved?

Farmasia Sdn. Bhd. have de-registered the medical device Bio-Aquacel Eye Safe from the Medical Device Authority effective 30<sup>th</sup> August 2023. This is to ensure the product is no longer in the market and accessible to the public at large.



**FARMASIA**

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System's instructions for use. Your personnel should maintain awareness over an appropriate defined period.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority (MDA)** will be informed of this notice.

Sincerely Yours,

For and on behalf of FARMASIA SDN. BHD.



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**WAN RIZZAL BIN WAN ZAKI**  
GENERAL MANAGER

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