RAYDENT
Partnering Professionals. Creating Smiles.

4th December 2019

Field Safety Notice

To Whom It May Concern

cc: Chairman Medical Board and relevant Head of Departments

Restriction of use_MICRO 10 ENZYME

Raydent Supplies (S) Pte Ltd, in consultation with the Health Sciences Authority (HSA), is issuing the letter to inform users of **MICRO 10 ENZYME for batch No: W08805**.

Background/Description of Problem

A batch of the product ANIOSYME DD1, placed on the market by Laboratoires ANIOS, has been recalled. There is no microbial contamination was identified in other batches of this product. However, with an abundance of caution, a restriction of use of this product has been applied. This product should only be used for the treatment of medical devices that will go through sterilization. This applies to all these other batches of ANIOSYME DD1 in stock as of November 16, 2019.

MICRO 10 ENZYME being similar product to ANIOSYME DD1, *we extend this restriction of use to this product you might have in stock.*

Advisory to Healthcare Professionals

Healthcare professionals are advised to do the following:

This Micro 10 Enzyme product for batch No: W08805 *should only be used for the treatment of medical devices that will go through sterilization.*

Reporting of Adverse Event
Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with these devices to *Ms Lily Quah* [redacted]. Alternatively, healthcare professionals may report the adverse events to the Medical Devices Branch, Health Products Regulation Group, HSA at Tel: 6866 1048, or report online at www.hsa.gov.sg/ae_online. Events that are reported to *Raydent Supplies (S) Pte Ltd* will be investigated and subsequently reported to HSA.

Please acknowledge receipt of this communication by returning at your earliest convenience - but no later than 15/12/2019 - the completed, dated and signed letter. We remain at your disposal for any question or assistance that you may need.

Please accept our apologies for the inconvenience it may have caused.

Yours Sincerely,

Raydent Supplies (S) Pte Ltd
6 Ubi Road 1, Wintech Centre, Singapore 408726
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T| 6741 5411 F| 6742 3593

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[redacted]

Ms Jean Chng
General Manager

Customer Action undertaken on behalf of Healthcare Organization

I confirm receipt of the Field Safety Notice (FSN) and that I read and understood its content.

Customer Details

Customer Number : _____

Customer Name : _____

Contact Name : _____

Telephone : _____

Fax : _____

Email : _____

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