

FIELD SAFETY NOTICE

REDUCTION IN SHELF LIFE OF SURGICAL NON-ABSORBABLE SUTURE DEVICES

Date: 3rd October 2024

Attention to all users affected by the devices mentioned in this notice.

Dear Valued Customer,

We are writing to inform you of important changes to the shelf life of the following medical devices. The shelf life adjustments are being implemented following changes in our packaging equipment, which prompted a revised packaging validation. We have determined that a reduction in the shelf life during stability study is necessary to ensure our products continue to meet the highest standards of safety and efficacy throughout their intended shelf life.

The updated shelf life of the affected devices is as follows:


Product Name	Previous Shelf Life	New Shelf Life
SURGICAL NON ABSORBABLE SUTURES MEASSILK	5 years	2 years
SURGICAL NON ABSORBABLE SUTURE DSUCI NAYLENE	5 years	3 years 6 months
SURGICAL NON ABSORBABLE SUTURE DSUCI MESALON	5 years	3 years 6 months

The following actions are required:

1. Identify any inventory of the affected products with the previous shelf life. Ensure that the affected stock is removed from your inventory for exchange activities. Refer to **Appendix A** for the affected lots that exceed the new shelf life and **Appendix B** for the affected lots that are still within the new shelf life.
2. Distribute this notice to all those who need to be aware of the Field Safety Notice within your organization.
3. Complete the attached acknowledgement receipt and return to our representative so that we may acknowledge your receipt of this notification.

For information, using these devices beyond their intended shelf life may affect product performance and effectiveness to users.

We sincerely apologize for any difficulties or inconvenience that this may cause. Please be informed that Muzamal is working towards improving the shelf life of our products and committed to deliver the highest quality products. We appreciate your assistance in this process.

If you have any questions or need further information, please do not hesitate to contact us. 

Sincerely,



MUHAMMAD MUZA BIN MUHAYEN
CEO
MUZAMAL INDUSTRIES SDN BHD
Date: 3/10/2024

Appendix A - Affected lots that exceed the new shelf life

PRODUCT NAME	NO	IDENTIFIER/ PRODUCT CODE	AFFECTED LOT NUMBER	MFG DATE	OLD EXPIRY DATE	NEW EXPIRY DATE	QUANTITY
SURGICAL NON ABSORBABLE SUTURE DSUCI MESALON	1	DK20GBC3-38	2007ME0008	Jul-20	Jul-25	Jan-24	144
	2	DK20GBC3-24	2103ME0009	Mar-21	Mar-26	Sep-24	312
	3	DK40CBC3-19	2007ME0003	Jul-20	Jul-25	Jan-24	288
	4	DK30GBC3-24	2006ME0003	Jun-20	Jun-25	Dec-23	360
	5	DK30GBC3-24	2006ME0004	Jun-20	Jun-25	Dec-23	360
	6	DK30GBC3-24	2006ME0005	Jun-20	Jun-25	Dec-23	360
	7	DK30GBC3-24	2101ME0007	Jan-21	Jan-26	Jul-24	360
	8	DK30GBC3-24	2101ME0008	Jan-21	Jan-26	Jul-24	360
	9	DK40GBC3-19	2012ME0018	Dec-20	Dec-25	Jun-24	360
	10	DK40GBC3-24	2005ME0009	May-20	May-25	Nov-23	324
	11	DK40GBC3-24	2005ME0007	May-20	May-25	Nov-23	360
	12	DK40GBC3-24	2005ME0008	May-20	May-25	Nov-23	360
	13	DK40GBC3-24	2008ME0003	Aug-20	Aug-25	Feb-24	360
	14	DK40GBC3-24	2104ME0002	Apr-21	Apr-26	Oct-24	360
	15	DK50GBC3-16	1805ME0010	May-18	May-25	Nov-21	360
	16	DK50GBC3-16	1805ME0007	May-18	May-25	Nov-21	1056
SURGICAL NON ABSORBABLE SUTURE MEASSILK	1	DM20GXC3-24	2005ME0010	May-20	May-25	May-22	240
	2	DM30CXC2-22	2207ME0004	Jul-22	Jul-27	Jul-24	360
	3	DM30GXC3-26	2205ME0009	May-22	May-27	May-24	480
	4	DM40GXC3-19	2201ME0011	Jan-22	Jan-27	Jan-24	468
	5	DM40GXC3-19	2201ME0007	Jan-22	Jan-27	Jan-24	420
	6	DM40GXC3-19	2108ME0002	Aug-21	Aug-26	Aug-23	360
	7	DMA0GXC3-30	2201ME0010	Jan-22	Jan-27	Jan-24	360
	8	DMA0GXC3-30	2201ME0008	Jan-22	Jan-27	Jan-24	480
	9	DMA2GXA2-40	2207ME0001	Jul-22	Jul-27	Jul-24	360
	10	DM30GXC3-24	2006ME0001	Jun-20	Jun-25	Jun-22	276
	11	DM30GXC3-24	2201ME0006	Jan-22	Jan-27	Jan-24	516
	12	DM30GXC3-24	2209ME0003	Sep-22	Sep-27	Sep-24	480
	13	DM20GXA2-26	2001ME0011	Jan-20	Jan-25	Jan-22	360
	14	DM20GXC3-26	2005ME0011	May-20	May-25	May-22	360
	15	DM20GXC3-26	2006ME0002	Jun-20	Jun-25	Jun-22	360
	16	DM20GXC3-26	2005ME0005	May-20	May-25	May-22	360
	17	DM20GXC3-26	2006ME0015	Jun-20	Jun-25	Jun-22	360
	18	DM20GXC3-26	2006ME0016	Jun-20	Jun-25	Jun-22	360
	19	DM20GXC3-26	2111ME0021	Nov-21	Nov-26	Nov-23	372
	20	DM20GXC3-26	2203ME0002	Mar-22	Mar-27	Mar-24	480
	21	DM20GXC3-26	2207ME0006	Jul-22	Jul-27	Jul-24	360
	22	DM20GXC3-26	2207ME0007	Jul-22	Jul-27	Jul-24	648
	23	DMA1GXC3-37	2208ME0001	Aug-22	Aug-27	Aug-24	528
	24	DMA1GXC3-37	2208ME0002	Aug-22	Aug-27	Aug-24	432
	25	DMA1GXC3-37	2209ME0006	Sept-22	Sept-27	Sept-24	480
	26	DMA1GXC3-37	2209ME0007	Sept-22	Sept-27	Sept-24	360
	27	DMA1GXC3-37	2101ME0009	Jan-21	Jan-26	Jan-23	360
	28	DMA0GXA2-40	2005ME0006	May-20	May-25	May-22	360
	29	DM40CXC3-16	2007ME0004	Jul-20	Jul-25	Jul-22	360
	30	DM40CXC3-16	2007ME0005	Jul-20	Jul-25	Jul-22	360
	31	DM40CXC3-16	2007ME0006	Jul-20	Jul-25	Jul-22	360
	32	DM40CXC3-16	2007ME0007	Jul-20	Jul-25	Jul-22	360
	33	DM40CXC3-16	2009ME0002	Sep-20	Sep-25	Sep-22	360
	34	DM40CXC3-16	2009ME0003	Sep-20	Sep-25	Sep-22	360
	35	DM40CXC3-16	2010ME0003	Oct-20	Oct-25	Oct-22	360
	36	DM40CXC3-16	2010ME0002	Oct-20	Oct-25	Oct-22	360
	37	DM40CXC3-16	2010ME0006	Oct-20	Oct-25	Oct-22	360
	38	DM40CXC3-16	2009ME0004	Sep-20	Sep-25	Sep-22	144
	39	DM40CXC3-16	2010ME0007	Oct-20	Oct-25	Oct-22	336
	40	DM40CXC3-19	2206ME0010	Jun-22	Jun-27	Jun-24	240

	41	DM40GXC3-16	2012ME0006	Dec-20	Dec-25	Dec-22	360
	42	DM40GXC3-16	1912ME0006	Dec-19	Dec-24	Dec-21	72
	43	DM40GXC3-16	2001ME0003	Jan-20	Jan-25	Jan-22	144
	44	DM50GXC3-12	2201ME0004	Jan-22	Jan-27	Jan-24	360

Appendix B - Affected lots that are still within the new shelf life

PRODUCT NAME	NO.	IDENTIFIER/ PRODUCT CODE	AFFECTED LOT NUMBER	MFG DATE	OLD EXPIRY DATE	NEW EXPIRY DATE	QUANTITY
SURGICAL NON ABSORBABLE SUTURE DSUCI NAYLENE	1	DJ70GBA2-19	2305ME0009	May-23	May-28	Nov-26	360
SURGICAL NON ABSORBABLE SUTURE DSUCI MESALON	1	DK40GXC3-19	2203ME0005	Mar-22	Mar-27	Sep-25	360
	2	DKA0GBC3-38	2201ME0013	Jan-22	Jan-27	Jul-25	240
	3	DK30GBC3-18	2303ME0006	Mar-23	Mar-28	Sep-26	456
	4	DK30GBC3-18	2303ME0007	Mar-23	Mar-28	Sep-26	24
	5	DK30GBC3-26	2303ME0009	Mar-23	Mar-28	Sep-26	480
	6	DK30GBA2-22	2303ME0008	Mar-23	Mar-28	Sep-26	468
	7	DK30GBA2-22	2306ME0001	Jun-23	Jun-28	Dec-26	12
	8	DKA2GBA2-40	2201ME0009	Jan-22	Jan-27	Jul-25	240
	9	DKA0GBA2-26	2301ME0005	Jan-23	Jan-28	Jul-26	468
	10	DKA0GBA2-26	2301ME0006	Jan-23	Jan-28	Jul-26	12
	11	DKA1GBC3-30	2210ME0005	Oct-22	Oct-27	Apr-26	480
	12	DKA1GBC3-30	2210ME0006	Oct-22	Oct-27	Apr-26	240
	13	DK20GBC3-38	2301ME0002	Jan-23	Jan-28	Jul-26	480
	14	DK20GBC3-38	2301ME0022	Jan-23	Jan-28	Jul-26	240
	15	DK40GBC2-20	2204ME0003	Apr-22	Apr-27	Oct-25	480
	16	DK60GBC3-12	2405ME0013	May-24	May-29	Nov-27	480
	17	DK20GBC3-24	2204ME0001	Apr-22	Apr-27	Oct-25	480
	18	DK20GBC3-24	2204ME0002	Apr-22	Apr-27	Oct-25	480
	19	DK20GBC3-24	2209ME0001	Sep-22	Sep-27	Mar-26	480
	20	DK20GBC3-24	2209ME0002	Sep-22	Sep-27	Mar-26	468
	21	DK20GBC3-24	2210ME0004	Oct-22	Oct-27	Apr-26	480
	22	DK20GBC3-24	2307ME0001	Jul-23	Jul-28	Jan-27	480
	23	DK20GBC3-24	2307ME0002	Jul-23	Jul-28	Jan-27	480
	24	DK20GBC3-30	2211ME0003	Nov-22	Nov-27	May-26	492
	25	DK20GBC3-30	2212ME0003	Dec-22	Dec-27	Jun-26	480
	26	DK20GBC3-30	2301ME0001	Jan-23	Jan-28	Jul-26	348
	27	DK30GBC3-24	2201ME0005	Jan-22	Jan-27	Jul-25	480
	28	DK30GBC3-24	2207ME0008	Jul-22	Jul-27	Jan-26	468
	29	DK30GBC3-24	2207ME0009	Jul-22	Jul-27	Jan-26	468
	30	DK30GBC3-24	2208ME0005	Aug-22	Aug-27	Feb-26	480
	31	DK30GBC3-24	2210ME0002	Oct-22	Oct-27	Apr-26	480
	32	DK30GBC3-24	2210ME0001	Oct-22	Oct-27	Apr-26	492
	33	DK30GBC3-24	2211ME0005	Nov-22	Nov-27	May-26	480
	34	DK30GBC3-24	2211ME0006	Nov-22	Nov-27	May-26	480
	35	DK30GBC3-24	2209ME0008	Sep-22	Sep-27	Mar-26	480
	36	DK30GBC3-24	2211ME0004	Nov-22	Nov-27	May-26	480
	37	DK30GBC3-24	2211ME0011	Nov-22	Nov-27	May-26	480
	38	DK30GBC3-24	2304ME0007	Apr-23	Apr-28	Oct-26	456
	39	DK30GBC3-24	2306ME0002	Jun-23	Jun-28	Dec-26	480
	40	DK30GBC3-24	2306ME0003	Jun-23	Jun-28	Dec-26	468
	41	DK30GBC3-24	2211ME0007	Nov-22	Nov-27	May-26	480
	42	DK30GBC3-24	2309ME0001	Sep-23	Sep-28	Mar-27	480
	43	DK30GBC3-24	2309ME0003	Sep-23	Sep-28	Mar-27	480
	44	DK30GBC3-24	2309ME0002	Sep-23	Sep-28	Mar-27	480
	45	DK30GBC3-24	2309ME0004	Sep-23	Sep-28	Mar-27	480
	46	DK30GBC3-24	2309ME0005	Sep-23	Sep-28	Mar-27	72

	47	DK40GBC3-16	2301ME0003	Jan-23	Jan-28	Jul-26	468
	48	DK40GBC3-16	2301ME0004	Jan-23	Jan-28	Jul-26	12
	49	DK40GBC3-19	2202ME0001	Feb-22	Feb-27	Aug-25	480
	50	DK40GBC3-19	2207ME0005	Jul-22	Jul-27	Jan-26	468
	51	DK40GBC3-19	2303ME0001	Mar-23	Mar-28	Sep-26	480
	52	DK40GBC3-19	2309ME0011	Sep-23	Sep-28	Mar-27	480
	53	DK40GBC3-19	2305ME0008	May-23	May-28	Nov-26	480
	54	DK40GBC3-19	2310ME0001	Oct-23	Oct-28	Apr-27	480
	55	DK40GBC3-19	2403ME0005	Mar-24	Mar-29	Sep-27	132
	56	DK40GBC3-24	2106ME0008	Jun-21	Jun-26	Dec-24	360
	57	DK40GBC3-24	2108ME0003	Aug-21	Aug-26	Feb-25	360
	58	DK40GBC3-24	2108ME0004	Aug-21	Aug-26	Feb-25	360
	59	DK40GBC3-24	2208ME0004	Aug-22	Aug-27	Feb-26	480
	60	DK40GBC3-24	2209ME0009	Sep-22	Sep-27	Mar-26	480
	61	DK40GBC3-24	2210ME0003	Oct-22	Oct-27	Apr-26	480
	62	DK40GBC3-24	2211ME0008	Nov-22	Nov-27	May-26	480
	63	DK40GBC3-24	2211ME0012	Nov-22	Nov-27	May-26	480
	64	DK40GBC3-24	2303ME0003	Mar-23	Mar-28	Sep-26	480
	65	DK40GBC3-24	2307ME0003	Jul-23	Jul-28	Jan-27	480
	66	DK40GBC3-24	2307ME0004	Jul-23	Jul-28	Jan-27	132
	67	DK50CBC3-19	2209ME0005	Sep-22	Sep-27	Mar-26	360
	68	DK50CBC3-19	2301ME0011	Jan-23	Jan-28	Jul-26	480
	69	DK50CBC3-19	2111ME0020	Nov-21	Nov-26	May-25	360
	70	DK50CBC3-19	2209ME0004	Sep-22	Sep-27	Mar-26	480
	71	DK50GBC3-16	2111ME0022	Nov-21	Nov-26	May-25	360
	72	DK50GBC3-16	2201ME0001	Jan-22	Jan-27	Jul-25	480
	73	DK50GBC3-16	2201ME0002	Jan-22	Jan-27	Jul-25	480
	74	DK50GBC3-16	2201ME0003	Jan-22	Jan-27	Jul-25	480
	75	DK50GBC3-16	2304ME0003	Apr-23	Apr-28	Oct-26	480
	76	DK50GBC3-16	2306ME0010	Jun-23	Jun-28	Dec-26	480
	77	DK50GBC3-16	2306ME0011	Jun-23	Jun-28	Dec-26	480
	78	DK50GBC3-16	2401ME0001	Jan-24	Jan-29	Jul-27	492
	79	DK50GBC3-16	2402ME0010	Feb-24	Feb-29	Aug-27	60
	80	DK50GBC3-16	2402ME0009	Feb-24	Feb-29	Aug-27	480
	81	DK50GBG3-13	2305ME0004	May-23	May-28	Nov-26	468
	82	DK50GBG3-13	2305ME0005	May-23	May-28	Nov-26	12
	83	DK50GBG3-18	2305ME0006	May-23	May-28	Nov-26	480
	84	DK60GBC3-12	2304ME0005	Apr-23	Apr-28	Oct-26	480
	85	DK60GBC3-12	2405ME0014	May-24	May-29	Nov-27	480
	86	DK60GBC3-16	2105ME0003	May-21	May-26	Nov-24	360
	87	DK60GBC3-16	2105ME0004	May-21	May-26	Nov-24	120
SURGICAL NON ABSORBABLE SUTURE MEASSILK	1	DM30GXC3-26	2304ME0006	Apr-23	Apr-28	Apr-25	240
	2	DM40GXC3-19	2211ME0010	Nov-22	Nov-27	Nov-24	480
	3	DM40GXC3-19	2211ME0014	Nov-22	Nov-27	Nov-24	480
	4	DM40GXC3-19	2310ME0003	Oct-23	Oct-28	Oct-25	312
	5	DM30GXC3-24	2303ME0004	Mar-23	Mar-28	Mar-25	480
	6	DM30GXC3-24	2303ME0005	Mar-23	Mar-28	Mar-25	480
	7	DM30GXC3-24	2309ME0009	Sep-23	Sep-28	Sep-25	360
	8	DM20GXA2-26	2308ME0017	Aug-23	Aug-28	Aug-25	480
	9	DM20GXA2-26	2302ME0007	Feb-23	Feb-28	Feb-25	564
	10	DM20GXA2-26	2302ME0008	Feb-23	Feb-28	Feb-25	36
	11	DM20GXC3-26	2211ME0009	Nov-22	Nov-27	Nov-24	480
	12	DM20GXC3-26	2211ME0013	Nov-22	Nov-27	Nov-24	480
	13	DM20GXC3-26	2301ME0021	Jan-23	Jan-28	Jan-25	480
	14	DM20GXC3-26	2301ME0020	Jan-23	Jan-28	Jan-25	456

15	DM20GXC3-26	2305ME0003	May-23	May-28	May-25	480
16	DM20GXC3-26	2307ME0005	Jul-23	Jul-28	Jul-25	480
17	DM20GXC3-26	2307ME0006	Jul-23	Jul-28	Jul-25	492
18	DM20GXC3-26	2307ME0007	Jul-23	Jul-28	Jul-25	480
19	DM20GXC3-26	2307ME0008	Jul-23	Jul-28	Jul-25	588
20	DM20GXC3-26	2309ME0007	Sep-23	Sep-28	Sep-25	516
21	DM20GXC3-26	2309ME0028	Sep-23	Sep-28	Sep-25	480
22	DM20GXC3-26	2309ME0008	Sep-23	Sep-28	Sep-25	480
23	DM20GXC3-26	2311ME0001	Nov-23	Nov-28	Nov-25	960
24	DM20GXC3-26	2311ME0002	Nov-23	Nov-28	Nov-25	960
25	DM20GXC3-26	2311ME0003	Nov-23	Nov-28	Nov-25	960
26	DM20GXC3-26	2311ME0004	Nov-23	Nov-28	Nov-25	960
27	DM20GXC3-26	2311ME0007	Nov-23	Nov-28	Nov-25	480
28	DM20GXC3-26	2311ME0005	Nov-23	Nov-28	Nov-25	960
29	DM20GXC3-26	2311ME0006	Nov-23	Nov-28	Nov-25	252
30	DM20GXC3-26	2403ME0006	Mar-24	Mar-29	Mar-26	480
31	DM20GXC3-26	2403ME0007	Mar-24	Mar-29	Mar-26	480
32	DM20GXC3-26	2403ME0008	Mar-24	Mar-29	Mar-26	480
33	DM20GXC3-26	2403ME0009	Mar-24	Mar-29	Mar-26	468
34	DM20GXC3-26	2403ME0010	Mar-24	Mar-29	Mar-26	252
35	DM30CXC3-19	2305ME0001	May-23	May-28	May-25	432
36	DM50GXC3-16	2308ME0014	Aug-23	Aug-28	Aug-25	720
37	DM20GXA2-20	2307ME0009	Jul-23	Jul-28	Jul-25	480
38	DM40GXA2-20	2308ME0001	Aug-23	Aug-28	Aug-25	960
39	DM40GXC3-16	2302ME0006	Feb-23	Feb-28	Feb-25	24
40	DM30GXA2-20	2211ME0001	Nov-22	Nov-27	Nov-24	480
41	DM30GXA2-20	2211ME0002	Nov-22	Nov-27	Nov-24	420
42	DM30GXA2-20	2305ME0002	May-23	May-28	May-25	480
43	DM30GXA2-20	2308ME0016	Aug-23	Aug-28	Aug-25	300
44	DM50GXA2-17	2308ME0012	Aug-23	Aug-28	Aug-25	480

muzamal® Industries

MOVING AHEAD TO A HEALTHIER TOMORROW
Manufacturer / Supplier of Medical Devices

Acknowledgement Receipt:

Kindly sign below to indicate your agreement to proceed with this product exchange:

Place: Intaniaga

Date: 1/11/2024

Name: MUHAMMAD AZMIZ

Position: SM SALES SUPPORT

Signature: 

Company stamp:



*We acknowledge receipt of the information in the FSN letter. We will return the affected lot to the manufacturer and will not request a replacement or exchange for new lots.



muzamal[®] Industries

MOVING AHEAD TO A HEALTHIER TOMORROW

Manufacturer / Supplier of Medical Devices

Acknowledgement Receipt:

Kindly sign below to indicate your agreement to proceed with this product exchange:

Place: Bogor

Date: 25 Oktober 2024

Name: Syarah Ruziq

Position: MR - PT. Muzamal Ventures Indonesia

Signature: 

Company stamp:



Remark: We acknowledge receipt of the information in the FSN letter
We will not return the affected lots to the manufacturer as we will use them as samples
for validation purposes. We also will not request a replacement or exchange for new lots

