



1400 Holcomb Bridge Road
Roswell, GA 30076

Date: November 22, 2013

To: Sterile Cleanroom Glove Customers

RE: Sterilization Paperwork Change for KIMTECH PURE* Cleanroom Sterile Gloves

Dear Valued KIMTECH Customer:

We are writing to inform you there will be a change in the Certificate of Irradiation and the Case Irradiation Sticker for the Kimberly-Clark KIMTECH PURE* Cleanroom Sterile Gloves. This change is a result of changes that our contracted sterilizer (SynergyHealth) recently informed us of. The impact of this change has been assessed by Kimberly-Clark and we have determined that the change **does not** impact the sterilization process or the gloves in anyway. The impact is related to how the documentation will look. Our team has worked diligently with SynergyHealth to ensure the required information is present on the paperwork. We have attached to this letter, examples of the current paperwork as well as the new look of the paperwork and case label. This change will be phased in starting with product that is sterilized on **January 1, 2014** and beyond. Customers can expect to see the changes as early as March 2014, depending on inventory levels.

Again, we would like to reassure you that all products will follow the same processes and procedures as before the change in paperwork/label. Kimberly-Clark will be monitoring this change closely to minimize any impacts to our customers. Depending upon when the product was sterilized, the Certificates of Irradiation and case irradiation labeling may reflect either the current SynergyHealth labeling or the new SynergyHealth labeling.

As a result of this change, you will notice changes in the sterilization labeling and the Certificates of Irradiation. The products affected by this change are as follows:

Glove	Codes	Alt Code
KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves	11821, 11822, 11823, 11824, 11825, 11826, 11827, 11828	N/A
KIMTECH PURE* G3 Sterile White Nitrile Gloves	56888, 56889, 56890, 56891, 56892, 56893, 56894, 56887	HC61160, HC61165, HC61170, HC61175, HC61180, HC61185, HC61190, HC61110

KIMTECH PURE* G3 Sterile Latex Gloves	56843, 56844, 56845, 56846, 56847, 56848, 56849, 56842	HC1360S, HC1365S, HC1370S, HC1375S, HC1380S, HC1385S, HC1390S, HC1310S
KIMTECH PURE* G5 Sterile Latex Gloves	56851, 56852, 56853, 56854, 56855, 56856, 56857, 56850	HC1160S, HC1165S, HC1170S, HC1175S, HC1180S, HC1185S, HC1190S, HC1110S

We have enclosed, for your examination, a copy of an example of the current SynergyHealth paperwork/label as well as the new SynergyHealth paperwork/label to show the differences in the old and new paperwork/label.

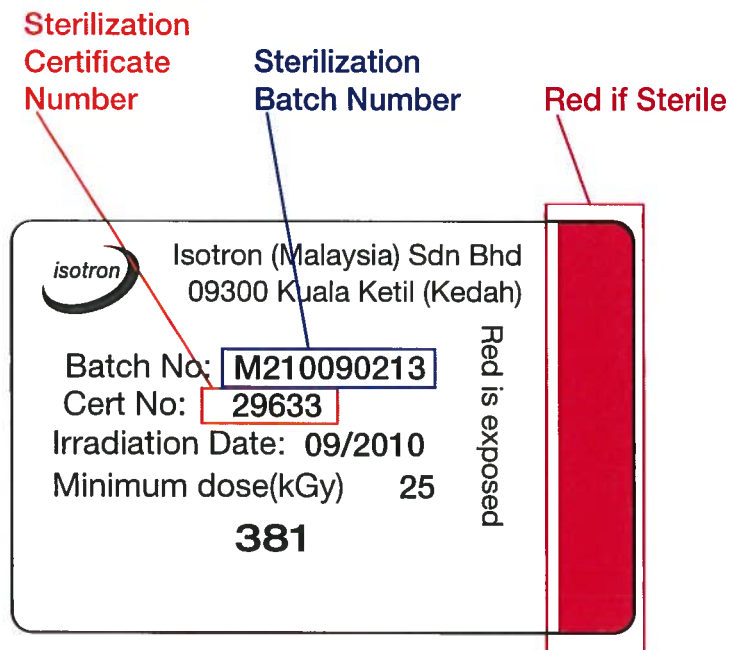
It is our hope that this letter of notification will satisfy any concerns concerning the change in look of the paperwork of our contracted sterilizer. We apologize for any inconvenience that this may have caused you and thank you for being a valued customer of Kimberly-Clark. Please feel free to contact us with any questions that you may have concerning this notification.

Sincerely,



Craig Johnson
Kimberly-Clark Professional Operations
Certified Quality Engineer

CURRENT CASE LABEL



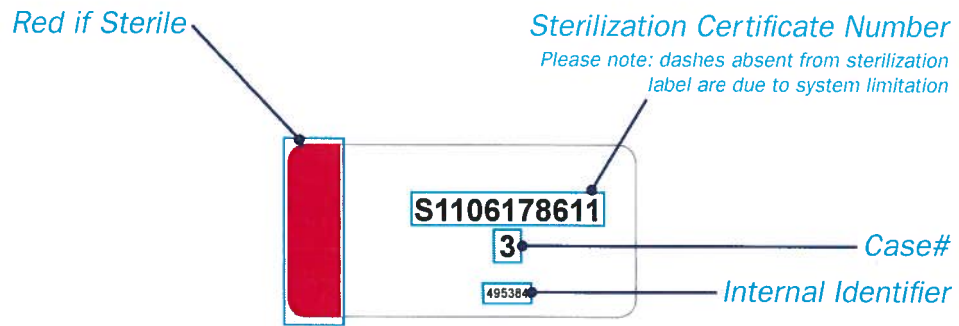
Sterilization Label

CURRENT CASE LABEL

NEW CASE LABEL

Sterilization Label

FOR REFERENCE ONLY



NEW CASE LABEL

CERTIFICATE OF IRRADIATION Number: **MA** 0029633

SAF005

SAFESKIN MEDICAL & SCIENTIFIC (THAILAND) LTD
 200 Moo 8, KANJANAVANICH ROAD
 TAMBOL PRIK
 AMPHUR SADA0, SONGKHLA
 THAILAND
 90120



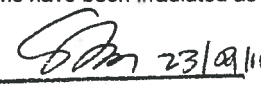
ISOTRON MALAYSIA Sdn Bhd
 Company No 512058-V
 Kuala Ketil Industrial Estate
 09300 Kuala Ketil, Kedah

Tel: 60 (0) 4 415 1111
 Fax: 60 (0) 4 415 1110
<http://www.isotron.com>

Cust. Ref: 4027002014
 Date Rec'd: 20/09/10
 Date: 22/09/10

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS																																																																								
M1SAF0050020 M210090213	KIMTECH Pure* G5, Sterile Latex Gloves, 12" Hand Specific Pairs	432	<table border="1"> <thead> <tr> <th>CAT NO</th> <th>MFG LOT/BATCH NO</th> <th>QTY</th> </tr> </thead> <tbody> <tr><td>HC1175S</td><td>280910/SM02452XX</td><td>36</td></tr> <tr><td>HC1175S</td><td>280910/SM02522XX</td><td>20</td></tr> <tr><td>HC1175S</td><td>280910/SM02522XX</td><td>36</td></tr> <tr><td>HC1175S</td><td>280910/SM02522XX</td><td>12</td></tr> <tr><td>HC1175S</td><td>280910/SM02522XX</td><td>24</td></tr> <tr><td>HC1175S</td><td>280910/SM02542XX</td><td>14</td></tr> <tr><td>HC1175S</td><td>280910/SM02542XX</td><td>8</td></tr> <tr><td>HC1175S</td><td>280910/SM02542XX</td><td>14</td></tr> <tr><td>HC1175S</td><td>280910/SM02542XX</td><td>16</td></tr> <tr><td>HC1180S</td><td>280910/SM02462XX</td><td>36</td></tr> <tr><td>HC1185S</td><td>280910/SM02512XX</td><td>36</td></tr> <tr><td>HC1185S</td><td>280910/SM02512XX</td><td>4</td></tr> <tr><td>HC1185S</td><td>280910/SM02522XX</td><td>6</td></tr> <tr><td>HC1185S</td><td>280910/SM02522XX</td><td>16</td></tr> <tr><td>HC1185S</td><td>280910/SM02542XX</td><td>10</td></tr> <tr><td>HC1165S</td><td>280910/SM02532XX</td><td>36</td></tr> <tr><td>HC1165S</td><td>280910/SM02532XX</td><td>10</td></tr> <tr><td>HC1165S</td><td>280910/SM02532XX</td><td>2</td></tr> <tr><td>HC1165S</td><td>280910/SM02532XX</td><td>24</td></tr> <tr><td>HC1190S</td><td>280910/SM02522XX</td><td>36</td></tr> <tr><td>HC1110S</td><td>280910/SM02562XX</td><td>7</td></tr> <tr><td>HC1110S</td><td>280910/SM02562XX</td><td>14</td></tr> <tr><td>HC1110S</td><td>280910/SM02562XX</td><td>15</td></tr> </tbody> </table> <p>IRRADIATION DATE: 21/09/2010</p> <p>DOSE REQUIRED: 25 - 50 kGy</p> <p>ACTUAL DOSE RECEIVED: MIN:25.5 kGy MAX:34.4 kGy</p>	CAT NO	MFG LOT/BATCH NO	QTY	HC1175S	280910/SM02452XX	36	HC1175S	280910/SM02522XX	20	HC1175S	280910/SM02522XX	36	HC1175S	280910/SM02522XX	12	HC1175S	280910/SM02522XX	24	HC1175S	280910/SM02542XX	14	HC1175S	280910/SM02542XX	8	HC1175S	280910/SM02542XX	14	HC1175S	280910/SM02542XX	16	HC1180S	280910/SM02462XX	36	HC1185S	280910/SM02512XX	36	HC1185S	280910/SM02512XX	4	HC1185S	280910/SM02522XX	6	HC1185S	280910/SM02522XX	16	HC1185S	280910/SM02542XX	10	HC1165S	280910/SM02532XX	36	HC1165S	280910/SM02532XX	10	HC1165S	280910/SM02532XX	2	HC1165S	280910/SM02532XX	24	HC1190S	280910/SM02522XX	36	HC1110S	280910/SM02562XX	7	HC1110S	280910/SM02562XX	14	HC1110S	280910/SM02562XX	15
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	Total	432	Last page 1 of 1																																																																								

This is to certify that the above items have been irradiated as specified above


TAI ENG THING
 QA Officer
 Isotron (Malaysia) Sdn Bhd

Authorised Signature:
 For and on behalf of **ISOTRON MALAYSIA Sdn Bhd**



www.synergyhealthplc.com

Sterilization Certificate Number

Please note: dashes absent from sterilization label are due to system limitation

Certificate of Irradiation

Date Issued: 11-Oct-2013

MY03 **S11061786-1-1**

This is to certify that Synergy Sterilization (M) Sdn. Bhd. has where appropriate delivered an irradiation process in accordance with:

- EN ISO 11137-1:2006 Sterilization of Health Care Products
- EN ISO 9001:2008 Quality Management System
- EN ISO 13485:2012 Quality System - Medical Devices

Safeskin Medical & Scientific (Thailand) Ltd
 200 MOO 8, KANJANAVANICH ROAD
 TAMBOL PRIK, AMPHUR SADAO
 SONGKHLA
 THAILAND
 THAILAND

FOR REFERENCE ONLY

Order Information

<p>Account Number: Synergy Health Sales Part Reference: Customer Reference Number: Product Description: Validation Reference: Quantity Received: Customer Minimum Specification kGy: Customer Maximum Specification kGy: Customer Unit Lot/Batch Number: Other Process Details:</p>	<p>101195 1024139 4027005031 KIMTECH PURE* G3 Sterile Sterling Nitrile Gloves, 12" Hand Specific Pairs 0.0358 72 25.0 50.0 SEE BELOW</p> <p style="text-align: right;"><i>Product Name</i></p> <p style="text-align: right;"><i>Irradiation Specification (Min/Max)</i></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;"></th> <th style="width: 25%; text-align: center;"><i>Code</i></th> <th style="width: 25%; text-align: center;"><i>Lot#</i></th> <th style="width: 35%; text-align: center;"><i>Batch#</i></th> </tr> </thead> <tbody> <tr> <td style="text-align: left;">CAT NO</td> <td style="text-align: center;">MFG.</td> <td style="text-align: center;">LOT/BATCH NO</td> <td style="text-align: center;">QTY</td> </tr> <tr> <td>11823</td> <td>970913</td> <td>SM32522VX</td> <td>31</td> </tr> <tr> <td>11823</td> <td>970913</td> <td>SM32562VX</td> <td>18</td> </tr> <tr> <td>11823</td> <td>970913</td> <td>SM32572VX</td> <td>18</td> </tr> <tr> <td>11823</td> <td>970913</td> <td>SM32572VX</td> <td>5</td> </tr> </tbody> </table>		<i>Code</i>	<i>Lot#</i>	<i>Batch#</i>	CAT NO	MFG.	LOT/BATCH NO	QTY	11823	970913	SM32522VX	31	11823	970913	SM32562VX	18	11823	970913	SM32572VX	18	11823	970913	SM32572VX	5
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Irradiation Data

<p>Date and Time of Irradiation: Reference Dose Range kGy: Calculated Minimum Dose kGy: Calculated Maximum Dose kGy:</p>	<p>11-Oct-2013 13:30 33.1 - 33.8 26.9 37.2</p> <p style="text-align: right;"><i>Actual Min/Max Dose</i></p>
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JAYANTHIMALA A.M.A.
 11/10/2013

Irradiation Release Authorized By Synergy Health plc

JAYANTHIMALA A.M.A.
 Malaysia QA & RA Manager
 Synergy Sterilization (M) Sdn. Bhd.