



**URGENT MEDICAL DEVICE RECALL**  
**NOTIFICATION LETTER**  
**Hygenic Dental Dam**

June 30, 2025

Dear Valued Customer,

This letter serves as notification of a voluntary recall of Hygenic Latex Dental Dam. Recall was initiated by The Hygenic Company, LLC for their Dental Dam – Latex due to the label on the bottom or back of the package incorrectly stating “latexfrei” next to the German or DE language bubble. All other languages on the label correctly state Latex and have the Latex symbol. We are notifying you since you may have purchased the affected product, which can be found in Table 1 below, from Performance Health.

Table 1: Impacted Product Information

| Performance Health Part Number | Manufacturer's Product Number | Product Name (Description)                    | Lot Number                       | Manufacturing Dates                                            | Distribution Dates    | Expiration Dates                                | Reason for Recall                                      |
|--------------------------------|-------------------------------|-----------------------------------------------|----------------------------------|----------------------------------------------------------------|-----------------------|-------------------------------------------------|--------------------------------------------------------|
| 15498                          | 15498                         | Hygenic Dental Dam, 6x6in, Green, Thin, 36/PK | 039A<br>046A<br>J191138          | February 2025-April 2025<br>2/8/2025<br>2/15/2025<br>4/23/2025 | 4/17/2025 - 6/18/2025 | 8/9/2028<br>8/16/2028<br>10/22/2028             | Incorrect translation of product description in German |
| 15499                          | 15499                         | Hygenic Dental Dam, 6x6in, Green, Med, 36/PK  | 342N1<br>039A<br>060A<br>J191137 | 12/7/2024<br>2/8/2025<br>3/1/2025<br>4/23/2025                 | 4/17/2025 - 5/29/2025 | 6/7/2028<br>8/9/2028<br>8/30/2028<br>10/22/2028 | Incorrect translation of product description in German |
| 15500                          | 15500                         | Hygenic Dental Dam, 6x6in, Green, Hvy, 36/PK  | 039A<br>J191136                  | February 2025-April 2025<br>2/8/2025<br>4/23/2025              | 4/17/2025 - 5/29/2025 | 7/10/2028<br>10/22/2028                         | Incorrect translation of product description in German |
| 15501                          | 15501                         | Hygenic Dental Dam, 6x6in, Green, Med, 360/PK | 342N1<br>J191135<br>J191896      | 12/7/2024<br>4/23/2025<br>5/27/2025                            | 4/17/2025 - 5/28/2025 | 6/7/2028<br>10/22/2028<br>11/25/2028            | Incorrect translation of product description in German |
| 15502                          | 15502                         | Hygenic Dental Dam, 6x6in, Green, Med, 52/PK  | 321N<br>J191134                  | 11/16/2024<br>4/23/2025                                        | 4/17/2025 - 5/28/2025 | 5/17/2028<br>10/22/2028                         | Incorrect translation of product description in German |

**Reason for Recall:**

Description of product in German incorrectly states the product is latex free., shown below.



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**Risk to Health:**

If a person has a sensitivity or allergy to latex products use of this product could result in an allergic reaction.

**Actions to be Taken by Customers:**

1. Immediately check your stock for the affected product numbers listed in the above table, which will be located on the product label shown below.



2. Please record the affected quantity on hand on the Form on the next page and return to Performance Health at the email address indicated on the Form.
3. A return label will be provided for on-hand units. Performance Health will replace the product.
4. If you are a distributor or have resold or transferred this product to another company or individual, you are requested to provide the information regarding sales of this product and contact information or agree to contact the distributor or customer. Please request that customer's document and return any affected product and include your customer's quantities on your response form.

Should you have any questions regarding these instructions, please contact us at [Quality@performancehealth.com](mailto:Quality@performancehealth.com).

We apologize for the inconvenience and thank you for your cooperation in this effort.

Best Regards,

Paul Hanneman,  
Vice President, Quality and Regulatory  
Performance Health



**URGENT MEDICAL DEVICE RECALL**  
Medline Alcohol Prep Pads

## Response Form

| Customer                   |                |
|----------------------------|----------------|
| Name:                      | Akura World sl |
| Account Number (if known): |                |
| Address:                   |                |

| Contact |  |
|---------|--|
| Name:   |  |
| Title:  |  |
| Email:  |  |
| Phone:  |  |

**Affected Product:**

| Performance Health Part Number | Manufacturer's Product Number | Product Name (Description)                   | Lot Number | Manufacturing Dates | Distribution Dates | Expiration Dates | Reason for Recall                                      |
|--------------------------------|-------------------------------|----------------------------------------------|------------|---------------------|--------------------|------------------|--------------------------------------------------------|
| 15499                          | 15499                         | Hygenic Dental Dam, 6x6in, Green, Med, 36/PK |            |                     |                    |                  | Incorrect translation of product description in German |
| 15500                          | 15500                         | Hygenic Dental Dam, 6x6in, Green, Hvy, 36/PK |            |                     |                    |                  | Incorrect translation of product description in German |

Total quantity on hand: \_\_\_\_\_

**Customer Signature:**

| Printed Name | Title | Signature | Date |
|--------------|-------|-----------|------|
|              |       |           |      |



**URGENT MEDICAL DEVICE RECALL**  
**Medline Alcohol Prep Pads**

## Response Form

| Customer                   |                                  |
|----------------------------|----------------------------------|
| Name:                      | Sigma Dental Systems Emasdi GmbH |
| Account Number (if known): |                                  |
| Address:                   |                                  |

| Contact |  |
|---------|--|
| Name:   |  |
| Title:  |  |
| Email:  |  |
| Phone:  |  |

**Affected Product:**

| Performance Health Part Number | Manufacturer's Product Number | Product Name (Description)                    | Lot Number | Manufacturing Dates | Distribution Dates | Expiration Dates | Reason for Recall                                      |
|--------------------------------|-------------------------------|-----------------------------------------------|------------|---------------------|--------------------|------------------|--------------------------------------------------------|
| 15498                          | 15498                         | Hygenic Dental Dam, 6x6in, Green, Thin, 36/PK |            |                     |                    |                  | Incorrect translation of product description in German |
| 15499                          | 15499                         | Hygenic Dental Dam, 6x6in, Green, Med, 36/PK  |            |                     |                    |                  | Incorrect translation of product description in German |
| 15500                          | 15500                         | Hygenic Dental Dam, 6x6in, Green, Hvy, 36/PK  |            |                     |                    |                  | Incorrect translation of product description in German |
| 15502                          | 15502                         | Hygenic Dental Dam, 6x6in, Green, Med, 52/PK  |            |                     |                    |                  | Incorrect translation of product description in German |

Total quantity on hand: \_\_\_\_\_

**Customer Signature:**

Return completed forms to: [Quality@PerformanceHealth.com](mailto:Quality@PerformanceHealth.com)



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Medline Alcohol Prep Pads

**Response Form**

| Printed Name | Title | Signature | Date |
|--------------|-------|-----------|------|
|              |       |           |      |