

FSN Ref: GCP402-P

FSCA Ref: GCP402-P

Date: 17.09.2025

**Urgent Field Safety Notice**  
**Device Commercial Name**

For Attention of\*:the patients,users,distributors,manufacturer and CH REP

Contact details of local representative (name, e-mail, telephone, address etc.)\*

Compan: Cosanum AG

Address:Brandstrasse 28 CH-8952 SchlierenSchweiz (Swiss)

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FSN Ref: GCP402-PFSCA Ref: GCP402-P

**Urgent Field Safety Notice (FSN)**  
**Device Commercial Name**  
**Risk addressed by FSN**

<b>1. Information on Affected Devices*</b>	
1	1. Device Type(s)*
.	<u>a device design as non -treated,absorbency foam material bonding with pp sticks for cleansing mouth,non- sterile</u>
1	2. Commercial name(s)
.	<u>Oral swab/Homedcare</u>
1	3. Unique Device Identifier(s) (UDI-DI)
.	<u>0 6975894820055</u>
1	4. Primary clinical purpose of device(s)*
.	<u>cleansing mouth and teeth in surgery,patient homecare,etc.</u>
1	5. Device Model/Catalogue/part number(s)*
.	<u>GCP402-P,GCP402-20P</u>
1	6. Software version
.	Only where relevant.
1	7. Affected serial or lot number range
.	<u>GCP402-P:LOT20240110,LOT24803923 ,LOT24813119, GCP402-20P:LOT20240110,LOT24803923 ,LOT24813119</u>
1	8. Associated devices
.	

<b>2 Reason for Field Safety Corrective Action (FSCA)*</b>	
2	1. Description of the product problem*
.	<u>The bonding strength is weak,the foam head take off from the stick among usage.</u>
2	2. Hazard giving rise to the FSCA*
.	<u>the patient will swallow the foam head when the foam head take off, have a potential trisk to suffocate.</u>
2	3. Probability of problem arising
.	<u>If patient can not indenpendent swallowing,the foam head will be inside throat</u>
2	4. Predicted risk to patient/users
.	<u>take a risk of suffocate to patient,although the very low probability.</u>
2	5. Further information to help characterise the problem
.	<u>The quality standard for the device is allowing 2 pcs weak strenght in 5000pcs.</u>
2	6. Background on Issue
.	<u>we know the issue will take a risk to users or patients,we always keep working on improving the produce process to ensure everyone is good,we have done some effective actions on the issue,e.g. add the glue into foam head and do 100% visual inspect on glue injection,chsngce the foam density to be 28g/m3 to decrease the foam hole diameter so that the surface area between foam and sticks are much more bigger.</u>
2	7. Other information relevant to FSCA
.	<u>will do corrective action verify in the following several orders.</u>

<b>3. Type of Action to mitigate the risk*</b>	
<b>3.</b>	<p><b>1. Action To Be Taken by the User*</b></p> <p> <input type="checkbox"/> Identify Device    <input type="checkbox"/> Quarantine Device    <input type="checkbox"/> Return Device    <input checked="" type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input type="checkbox"/> Other                      <input type="checkbox"/> None </p> <p>Provide further details of the action(s) identified.</p>
<b>3.</b>	<p><b>2. By when should the action be completed?</b></p> <p style="text-align: right;"><u>check before usage</u></p>
<b>3.</b>	<p><b>3. Particular considerations for:</b>                      Choose an item.</p> <p>Is follow-up of patients or review of patients' previous results recommended? Choose an item.</p> <p><u>no need to patient-level follow up</u></p>
<b>3.</b>	<p><b>4. Is customer Reply Required? *</b>                      <u>No</u> (If yes, form attached specifying deadline for return)</p>
<b>3.</b>	<p><b>5. Action Being Taken by the Manufacturer</b></p> <p> <input type="checkbox"/> Product Removal                      <input checked="" type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Software upgrade                      <input type="checkbox"/> IFU or labelling change </p> <p> <input type="checkbox"/> Other                                      <input type="checkbox"/> None </p> <p><u>add 100% inspect on visual inspect and meanwhile enhance sampling inspect level</u></p>
<b>3</b>	<p><b>6. By when should the action be completed?</b></p> <p style="text-align: right;"><u>2025-08-20---2025-12-20</u></p>
<b>3.</b>	<p><b>7. Is the FSN required to be communicated to the patient /lay user?</b>                      <u>No</u></p>
<b>3</b>	<p><b>8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?</b></p> <p>Choose an item.                      Choose an item.</p>

<b>4. General Information*</b>	
4.	1. FSN Type* <span style="float: right;"><u>New</u></span>
4.	2. For updated FSN, reference number and date of previous FSN <span style="float: right;">Provide reference and date of previous FSN if relevant</span>
4.	3. For Updated FSN, key new information as follows: Summarise any key difference in devices affected and/or action to be taken.
4.	4. Further advice or information already expected in follow-up FSN? * <span style="float: right;"><u>NO</u></span>
4	5. If follow-up FSN expected, what is the further advice expected to relate to:  <u>—</u>
4	6. Anticipated timescale for follow-up FSN <span style="float: right;">For provision of updated advice.</span>
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name <span style="float: right;"><u>Ningbo KeRui Hygien Product Co.,Ltd</u></span>
	b. Address <span style="float: right;"><u>No.1599,Juxian Road,High-tech zone,Yinzhou district,Ningbo,315040,China</u></span>
	c. Website address <span style="float: right;"><u>www.greencare-hygiene.com</u></span>
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *
4.	9. List of attachments/appendices: <span style="float: right;">If extensive consider providing web-link instead.</span>
4.	10. Name/Signature <span style="float: right;"><u>Bruce Wan/Quality Manager</u></span>

<b>Transmission of this Field Safety Notice</b>	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*</p>

Note: Fields indicated by \* are considered necessary for all FSNs. Others are optional.