

## URGENT SITE SECURITY NOTICE

For the kind attention of:  
Medical Devices Distributors  
Health Management

Canelli, 25/03/2021

Internal Aptaca Reference – R. 01.2021

Ref: Medical Devices sterilized at the Steril M

**This document contains important information for your product. It is therefore recommended that you communicate this safety notice and related recommended corrective actions to all potential users in your facility.**

**Print and keep this document for archiving.**

<b>Security problem</b>	Aptaca was informed by the Steril Milano sterilization service provider of possible deviations of the parameters / processes defined for ethylene oxide sterilization, already validated and routinely used.
<b>Safety Instructions</b>	Block the devices, do not use them and / or put them on the market. Contact the Manufacturer for the return of the device (withdrawal from the market).
<b>Product details</b>	REF item: <b>4002/SG/CS</b> Lot: <b>60CL20</b> RDM <b>1900310/R</b>
<b>Manufacturer Actions</b>	<ul style="list-style-type: none"> <li>- Aptaca has suspended any collaboration relationship with the Steril Milano supplier</li> <li>- Complete traceability of the Devices and lots involved was carried out. The material still in stock in its warehouses was promptly blocked and segregated.</li> <li>- The Customers to whom the DMs object of non-compliance have been provided have been identified and a formal communication has been sent so that they can block any material in their warehouses and so that they can do the same with their Clients.</li> <li>- Strengthening the plan for verifying the sterility of sterilized devices</li> </ul>
<b>Contact info</b>	If you have any questions regarding this corrective action 'in the field' or how to identify the devices involved, you can contact the Quality Department at: TEL: (+39) 0141 83.50.75 Email: <a href="mailto:qualita@aptaca.com">qualita@aptaca.com</a> - <a href="mailto:qra@aptaca.com">qra@aptaca.com</a> - <a href="mailto:info.italia@aptaca.com">info.italia@aptaca.com</a>

Aptaca S.p.A. confirms that the following informations has been communicated to the Competent Authorities.

Maintaining high levels of safety and quality is our top priority. For any questions, please contact Aptaca S.p.A. immediately.

Sincerely,  
Aptaca S.p.A.



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**MEDICAL DEVICE NOTIFICATION CONFIRMATION**

Please complete this form and return it to Aptaca S.p.a.  
This will confirm receipt and understanding of the Medical Device Correction Notice.

Customer  
name/consignee: \_\_\_\_\_

Address: \_\_\_\_\_

City / State / ZIP Code  
/ Country: \_\_\_\_\_

e-mail address: \_\_\_\_\_

Telephone number: \_\_\_\_\_

The user confirms that he has received and understood the attached Medical Device Correction Notice and acknowledges the actions taken by us, past or planned, in accordance with the Notice in question, as well as the fact that we have informed qualified personnel.

**Please provide the name of the responsible person who completed this form.**

Signature: \_\_\_\_\_

Printing name: \_\_\_\_\_

Title: \_\_\_\_\_

Date (DD/MM/YYYY): \_\_\_\_\_

**Please return the completed form by scanning it and sending it by e-mail to the following e-mail address: [qualita@aptaca.com](mailto:qualita@aptaca.com).**