Field Safety Notice

| REF-T38177 |

GETINGE ✳

Please forward this information to all relevant users, [biomedical staff for capital equipment, materials management and/or purchasing for consumables] and risk management department concerned in your facility

Subject: GSS67H

Products affected:

Product	Article No.	S/N or Batch No.
GSS67H		With software version earlier than 2.0.1

Dear Customer,

The purpose of this letter is to inform about a potential issue found in the sterilizer.
Our records indicate that your facility has received one or more of these devices.

Normal use and Indications

Under normal circumstances the sterilizer will perform as expected.

The following has been discovered

Under certain conditions, we have identified that an issue might prevent the device from performing as intended. If the sterilizer is connected to a network there is a possibility to change certain parameters from a remote computer. We are not aware of instances where this issue has led to any incidents.

Potential hazards

Unauthenticated remote access to the Getinge product over the network.   The remote access may result in control over the internal variables and programs. Its therefore theoretically possible for a potential attacker to render the machine unusable or manipulate the product settings which may compromise the intended use of the products or in the worst case the sterilization efficacy.

Precautions

The device can be used in accordance to the instructions for use, with extra attention to the following:

Switches, routers and firewalls must be configured to allow and block the traffic between the medical device and the desired servers and clients as detailed in the tables below.

Firewall and Router Settings

The following sections provide information that shall be used when setting up the connection to allow and block traffic to and from the medical device

Traffic to be Allowed:

Port and Protocol	Direction	Usage	Comment
3332/tcp	Inbound to this port and Outbound from this port to sender port.	T-DOC connection	Enable if using T-DOC
3400/tcp	Inbound to this port and Outbound from this port to sender port.	Sterilizer AGS	Enable if using a Sterilizer Air-Glide-System (AGS)
68/udp	Inbound to this port and Outbound from this port to sender port.	DHCP	Enable if using Reserved IP address from a DHCP server.
21/tcp FTP	Outbound to this port on a Network Printer or FTP Server, and Inbound from this port to the medical device.	Network Printing Network Storage (FTP Server)	Enable if using the network printing option or if using the Network Storage with FTP Server option.
ICMP echo request, ICMP echo reply	Outbound echo request and Inbound echo reply to and from the IP address of the network printer,	Network Printing Network Storage (FTP Server) Network Storage (CIFS Server)	Enable if using the network printing option or if using the Network Storage with FTP Server or CIFS Server option.
445/tcp 137/udp 139/tcp	Outbound to these ports on a Network Storage server (SMB/CIFS), and Inbound response from these ports to the medical device.	Network Storage (CIFS Server)	Enable if using Network Storage with CIFS server option.
443/tcp	Outbound to this port to a server on the Internet. Inbound from this server to the medical device.	Getinge Online	Enable when using the Getinge Online feature.
DNS	Outbound to local DNS server as configured by the DHCP assignment. Inbound from this server.	Getinge Online	Enable when using the Getinge Online feature.

Traffic to be Blocked

Blocked traffic is required to avoid potential hazardous situations that may arise from the network connection.

Traffic shall be blocked for the following products and ports:

Port and Protocol	Action	Products
11169/tcp	Block all Inbound and Outbound traffic.	Getinge Steam Sterilizer: GSS67H with System Software versions 1.3.4 and 1.3.5

Corrective action

A solution that will correct this issue has been developed.
Getinge will initiate an immediate field action of all affected device units. You will be contacted by your Getinge sales or service representative to plan for the update of your device.

Please maintain awareness of this notice and related actions until your sterilizer has been updated to ensure effectiveness of the corrective action.

We apologize for any inconvenience this may cause and we will do our outmost to carry through this action as swiftly as possible.

Should you have questions or require additional information, please contact your local Getinge representative.

Sincerely,

Karolina Olofsson　　　　　　　　　　　　Pia Brorson
Product Manager　　　　　　　　　　　　　Head of Quality
Getinge Infection Control AB　　　　　**Getinge Sterilization AB**