



## TECHNICAL FILE

TF – 02

### PRODUCT INFORMATION / USER MANUAL PRODUCT DESCRIPTION

Release date 05.02.2018 Revision date 09.09.2019 Revision number 03

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#### 01. 1. Product Name

PRODUCT NAME AND SIZE	GMDN CODE	GMDN NAME
<i>Non-Sterile Hydrophilic Gauze / Non-Sterile Gauze Compresses (Sponges) with / without XR</i>	48133	<i>Gauze Compresses (Sponges)with /without XR</i>
<i>Non-Sterile Lap Sponges with XR</i>	58802	<i>Gauze Compresses (Surgical Sponges)with XR</i>
<i>Non-Sterile Lap Sponges without XR</i>	44971	<i>Gauze Compresses (Surgical Sponges)/without XR</i>
<i>Non-Sterile Cotton Pads with /Without XR</i>	32572	<i>Cotton Pads With /without XR</i>

01.2. **Directive** Medical Device Directive 93 / 42 / EEC

**Classification** CLASS II $\alpha$ , ANNEX IX, RULE VI

01.4. **GMDN CODES** : 48133 – *Non-Sterile Gauze Compresses with /without XR (Sponges)*  
44971 - *Non-Sterile Gauze Compresses Lap Sponges without XR*  
58802 - *Non-Sterile Gauze Compresses Lap Sponges with XR*  
32572- *Non-Sterile Cotton Pads with /Without XR*

01.5. **User's Manual**

	<p><b>TECHNICAL FILE</b></p> <p><b>PRODUCT INFORMATION / USER MANUAL</b></p> <p><b>PRODUCT DESCRIPTION</b></p>	<p><b>TF – 02</b></p>			
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***Non-Sterile Gauze Compresses with /without XR (Sponges)***

*After sterilization, operations (except central nerve system and the central cardiac system) as sponge to clean the blood, at the medical dressing, as sponge to clean the blood and etc.. other secretions create a mechanical barrier to suppress.*

**Usage period of the products:** The products are in use. Therefore, the period of use is temporary. In other words, they are cute devices that are intended to be used in less than 60 minutes and renewed.  
It is suitable sterile for 20 minutes at 136 °C with the method of steam sterilization of the products.  
The products do not include any accessories.

***Non-Sterile Gauze Compresses Lap Sponges with /without XR***

*After sterilization, operations (except central nerve system and the central cardiac system) as sponge to clean the blood, at the medical dressing, as sponge to clean the blood and etc.. other secretions create a mechanical barrier to suppress. Gauze (Abdominal) compresses are used in the surgical operations (colon, stomach, thorax, etc.) to wrap the tissues and organs and control the bleeding as general surgery.*

**Usage period of the products:** The products are in use. Therefore, the period of use is temporary. In other words, they are cute devices that are intended to be used in less than 60 minutes and renewed.  
It is suitable sterile for 20 minutes at 136 °C with the method of steam sterilization of the products.  
The products do not include any accessories.

***Non-Sterile Cotton Pads with /Without XR***

*Operations (except central nerve system and the central cardiac system) as sponge to clean the blood, at the medical dressing, as sponge to clean the blood and etc.. other secretions create a mechanical barrier to suppress. The places where cotton pads are used are hygienic patient pad and gynecology as a wound dressing. It is also possible to use the Cotton Pad in abdominal operations.*

**Usage period of the products:** The products are in use. Therefore, the period of use is temporary. In other words, they are cute devices that are intended to be used in less than 60 minutes and renewed.  
It is suitable sterile for 20 minutes at 136 °C with the method of steam sterilization of the products.  
The products do not include any accessories.

It is non-sterile.

It is Single Use.

Do not use open, torn or perforated products.

Store in a cool, dry place.

The storage ambient temperature is between 15°C and 30°C.

Storage environment storage humidity limit should be between 0% and maximum 70%.

Protect from sun rays.



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	<b>Do Not Reuse</b>
	<b>Use By</b>
	<b>Non Sterile</b>
	<b>Batch Code</b>
	<b>Date Of Manufacture</b>
	<b>Manufacturer</b>
	<b>Do not use if package is damaged</b>
	<b>Temperature Limit</b>
	<b>Keep Dry</b>
	<b>Keep Away From Sunlight</b>
	<b>Humidity Limitation</b>

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	<p>Conformite European</p>
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**01.6. Shelf Life of the Product: 5 Year**