	TECHNICAL FILE PRODUCT INFORMATION / USER MANUAL PRODUCT DESCRIPTION	TF – 02			
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
Non-Sterile Hydrophilic Gauze / Non-Sterile Gauze Compresses (Sponges) with / without XR	48133	Gauze Compresses (Sponges)with /without XR
Non-Sterile Lap Sponges with XR	58802	Gauze Compresses (Surgical Sponges)with XR
Non-Sterile Lap Sponges without XR	44971	Gauze Compresses (Surgical Sponges)/without XR
Non-Sterile Cotton Pads with /Without XR	32572	Cotton Pads With /without XR

01.2. Directive Medical Device Directive 93 / 42 / EEC

Classification CLASS IIa, 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 style="text-align: center;">TECHNICAL FILE</p> <p style="text-align: center;">PRODUCT INFORMATION / USER MANUAL</p> <p style="text-align: center;">PRODUCT DESCRIPTION</p>				<p style="text-align: center;">TF – 02</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.




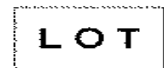







Store in a cool, dry place.


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

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01.6. Shelf Life of the Product: 5 Year