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LETTER FOR STERILIZATION DURATION

The underwritten company **SOGEVA srl** , with legal address in Ospitaletto (BS), Via Primo Maggio trav 3 nr 18, manufacturer of disposable device, non sterile, medical use, for the steam sterilization and the ethylene oxide sterilization, named **FLAT POUCHES, AUTOSEALING POUCHES, GUSSETTED POUCHES, FLAT REELS AND GUSSETTED REELS**, coupled with medical paper and plastic material poliestere polypropylene, under all the disposition of 93/42/CEE Directive regarding Medical Devices, Class I and conform to the requirements of Encl. I 93/42/CEE Directive, as descrive in Encl.VII of the above Directive and following the norms **UNI EN 867 UNI EN 868 UNI EN ISO 11140 UNI EN ISO 11607** and for disposition of **Directive 93/42/CEE regarding Medical Devices D.L. 46/97** object of the original **Declaration of Conformity** issued by Ministry of Health in first edition on **04/12/1997** ,

With this letter informs its customers

Sterility duration for ethylene oxide sterilization depends on correct and strict observance of the norms and the technical instructions for sterilization as per update norms both for law and end users (hospital or laboratory) and it is usually valid for 3 years. In this contexture SOGEVA srl declares that its devices in object are conforming with relative certification to norm UNI EN 868 .

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Sterility duration for steam depends on correct and strict observance of the norms and the technical instructions for sterilization as per update norms both for law and process for steam sterilization and on many variable conditions such as:

1) TYPOLOGY OF THE MEDICAL INSTRUMENT TO BE STERILIZED
2) TYPOLOGY OF THE THERMO-SEALER USED
3) TYPOLOGY OF AUTOCLAVE USED
4) TYPOLOGY OF THE STERILIZATION PROGRAM USED
5) TYPOLOGY OF STORAGE

Of course we cannot make evidence for each combination used the exact duration of sterility considering the infinity variations possible (think for example on how many different instruments you can sterilize or on the infinity typologys of autoclaves on the market) the company SOGEVA srl declares that the above mentioned devices are conforming and follows the certification relative to UNI EN 868 .

In this contexture SOGEVA srl, after verification on notices, the comments and the conventions existing at the moment, suggests the duration of sterility for steam in single pouch (usually used for non invasive used on laboratori and stay in bed operation unit) of 30 days and double pouch (usually used with " no touch " technique for medical device used for invasive procedures and for medical devices used in Surgery Unit) a duration of 60 days, on condition that in both cases you respect all the conditions suitable for conservation.

Preservation of sterility depends on type of packaging and storage conditions.
There are many factors which can compromise the efficency of antibacterial barrier assured by the package, depend on many variations: air contamination, powder and humidity, breaks on package surface, uncorrect opening and handling of the package.

It's essential to grant the **correct condition for storage and use of the material before sterilization process**; one of the most important thing is to protect it from sunlight, water and keep the protection of the plastic package and carton package, to be sure to not use the pouch if it is damaged.
It's essential to grant the **correct condition for storage and use of the material after sterlization process**; one of the most important thing i sto store it in closed and clean wardrobes, dry and protect from powder, with limited access to closed window and doors, with temperature 18/22 C° and humidity 35/50% , if stored on shelves – these have to be put on 20/25 cm from the floor , 40/50 under the ceiling and 15/20 from the wall; the boxes have to be stored in chronological order relative to the expiry, handled less as possible and with care.
The packages broken, damaged, opened, fallen down or wet must be considered as non-sterile and must be re-packed and sterilized again.

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REFERENCES:

"La sterilizzazione a vapore AQ03 REV 0/2003 Direzione Sanitaria Presidio Ospedaliero Centrale REGIONE LAZIO Protocollo Operativo e Procedure Tecniche ASL VITERBO "

"Metodi di sterilizzazione di presidi sanitari INFN TORINO Istituto Nazionale di Fisica Nazionale "

" STERLIZZAZIONE Wikipedia "

"Linee Guida sull'attivita' di sterilizzazione quale protezione collettiva da agenti biologici per l'operatore nelle strutture sanitarie (D.Lgs 626/94) "

"La sterilizzazione : competenze, responsabilita' e direttive IPASVI-ROMA"

"La sterilizzazione in Ospedale "

NORMS

D.L. 46/97 DIR 93/42/CEE
UNI CEI ISO 13485 :2004
UNI CEI EN ISO 14971.2004
UNI EN ISO 9000 :2005
UNI EN ISO 9001 : 2000
UNI EN 980 :2004
UNI EN ISO 11607
ISO 11140
UNI EN 285
UNI EN 550
UNI EN 554
UNI EN 556
UNI EN 866
UNI EN 867
UNI EN 868
UNI EN 1174
UNI EN ISO 11737
UNI EN ISO 14937
D.Lgs 626/94
D.Lgs 475/92
ISPESL D. 2638 del 26/02/2001
UNI EN ISO 11607

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