PROFESSIONAL MEDICAL PRODUCTS

ISTRUZIONI PER LA PULIZIA E LA STERILIZZAZIONE DI BACINELLE DI PLASTICA PER USO OSPEDALIERO

CLEANING AND STERILIZATION INSTRUCTION FOR HOSPITAL PLASTIC HOLLOWARES

MODE D'EMPLOI AVEC CONSIGNES POUR LE NETTOYAGE ET LA STÉRILISATION. POUR ACCESSOIRES POUR HÔPITAUX EN PLASTIQUE

MANUAL DE INSTRUCCIONES PARA LIMPIAR Y ESTERILIZAR PARA ACCESORIOS HOSPITALARIOS DE PLÁSTICO

INSTRUÇÕES DE LIMPEZA E ESTERILIZAÇÃO PARA RECIPIENTES DE PLÁSTICO HOSPITALARES

ΟΔΗΓΙΕΣ ΚΑΘΑΡΙΣΜΟΥ ΚΑΙ ΑΠΟΣΤΕΙΡΩΣΗΣ ΠΛΑΣΤΙΚΩΝ ΣΚΕΥΩΝ ΝΟΣΟΚΟΜΕΙΟΥ

È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.

All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.

Il est nécessaire de signaler tout accident grave survenu et lié au dispositif médical que nous avons livré au fabricant et à l'autorité compétente de l'état membre où on a le siège social.

Es necesario informar al fabricante y a la autoridad competente del Estado miembro en el que se encuentra la sede sobre cualquier incidente grave que haya ocurrido en relación con el producto sanitario que le hemos suministrado.

É necessário notificar ao fabricante e às autoridades competentes do Estado-membro onde ele está sediado qualquer acidente grave verificado em relação ao dispositivo médico fornecido por nós.

Σε περίπτωση που διαπιστώσετε οποιοδήποτε σοβαρό περιστατικό σε σχέση με την ιατρική συσκευή που σας παρέχουμε θα πρέπει να το αναφέρετε στον κατασκευαστή και στην αρμόδια αρχή του κράτους μέλους στο οποίο βρίσκεστε.

REF **37701 - 37702 - 37704 - 37705 - 37706 - 37707 - 37708**
37710 - 37711 - 37712 - 37715 - 37717 - 37718

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MD NON STERILE CE

M37701-M-Rev.4-10.26

Devices used for a variety of medical purposes, such as fluids container, body waste collector, holder/carrier for instruments, intended for medical use as support of the medical and/or surgical procedure in which they are used.

1. Cleaning

Clean before and after use. (The first and any time after use, the device must be cleaned with warm water, disinfected and rinsed if possible with distilled water and carefully dried).

2. Disinfection, rinsing and drying

Pay attention that only neutral cleaning agents and disinfectants without chlorine, ammonia, phenol, aldehydes that are suitable for cleaning and disinfecting plastic instruments are used.
Disinfectants must conform to the applicable national regulations for disinfectants (such as FDA approval and CE mark).
Dry all the parts with lint-free disposable cloths (do not use recycled cloths). Use oil-free compressed air to dry holes.

3. Sterilization

Non sterile, sterilize if required (European standard ISO 17665 i.e. steam sterilization for medical devices to be followed).
Sterilization is achieved by exposing products to saturated steam at high temperatures (121°C to 134°C). Product(s) are placed in device called the autoclave and heated through pressurized steam to kill all microorganisms including spores. The device's exposure time to steam would be anywhere between 3 to 15 minutes.

Examples of minimum temperatures and times established for adequate level of microbial lethality in sterilization processes (refer table – 1 of ISO/TS 17665-2).

Temperature (°C)	Time Minutes
121	15
126	10
134	03

4. The device showing damage or crack must be immediately replaced and not to be used

Recommended storage condition: device to be stored in clean and dry condition.

CE	Medical Device compliant with Regulation (EU) 2017/745	REF	Product code	NON STERILE	Non-sterile
	Caution: read instructions (warnings) carefully	LOT	Lot number		Keep away from sunlight
	Consult instructions for use		Manufacturer		Keep in a cool, dry place
	Date of manufacture		Temperature limit	%	Humidity limit
MD	Medical Device	UDI	Unique device identifier	UK REP	Authorized Representative in the UK
CH REP	Authorized Representative in Swiss				

GIMA WARRANTY TERMS
The Gima 12-month standard B2B warranty applies.