

PDS

Product Data Sheets

IRRIGATION LINE - 1.011.0633

- REFERENCES
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 - Annex 04 – STERILIZATION PROCESS VALIDATION
- DECLARATION AND APPLIED STANDARD

Rev00	Dec 2013	Prima emission / First emission - DRAFT
Rev01	10.12.2014	Modifica punto 6: modifica della linea secondo nuova campionatura lotto 14314 e modifica materiale componente (8) – aggiornamento Allegato 02 Update point 6: change of the line according the last samples lot14314 and change the material of the component (8) – update of the Annex 02
Rev02	10.02.2015	Inserimento codice prodotto cliente 1.011.0633; specifiche di confezionamento punto 5 e allegato 1 Addition of the KaVo code 1.011.0633; packaging details point 5 and Annex 1
Rev03	03.03.2015	Decisione finale del cliente sui alcuni materiali e componenti: <ul style="list-style-type: none"> - Definitivo OK della lunghezza dello spezzone pompa (componente 21) - Componente 8 in materiale ULTRASON BASF - Componente 6 in materiale APEC1745 (Bayer) trasparente - Incollaggio con Loctite tra componente 1 e 2 - Stampa di un numero seriale sul componente 5 Final decisions of he client: <ul style="list-style-type: none"> - Definitive OK about the pump tube length (component 21) - Component 8 in ULTRASON (BASF) material - Component 6 in in APEC1745 (Bayer) material, transparent - Component 1 and 2 assembled with Loctite glue - Printed serial number on component 5
Rev04	18.03.2015	Inserimento, in Allegato 2, della scheda tecnica della colla Loctite Addition, in Annex 2, of the Technical Data Sheet of the Loctite glue
Rev05	02.04.2015	Page 1:correction of product description Point 5: indication of IFU in second packaging Point 6: delete the indication of printed plastic key Addition of the “Declaration and applied standard” Annex 1: label and IFU to be defined
Rev06	15.05.2015	New proposal with disassembled spike (see point 6 – technical drawing) -annex 2: delete the technical data Sheet of the Loctite glue
Rev07	29.05.2015	New proposal with silicone junction between spike and irrigation line
Rev08	10.06.2015	Delete components luer in Annex 2 Update information in Annex 4

REFERENCES

OMNIA code	Ref KaVo	Description
30.F0341	1.011.0633	Sterilizable Hose Set S600

RE-USABLE TUBING FOR CONDUCTING AND PUMPING STERILE LIQUID TO THE IRRIGATION SYSTEM OF A HAND
PIECE OR CONTRA ANGLE.

TECHNICAL DATA SHEET

1. Product identification

Product is classified in Class IIa in accordance with Rule 5 of Annex IX to Directive 93/42/EEC (updated by Directive 2007/47/CE) and are CE marked 0546
GMDN code: 44772

2. General product description and Manufacturer identification

Omnia Spa
Via Francesco Delnevo 190 - 43036 Fidenza – Parma
Tel. 0524.527453 – Fax. 0524.525867 – www.omniaspa.eu
Distributed by:

KaVo Dental GmbH
Bismarcking 39
88400 Biberach/Riß
Tel.: +49 (0) 7351 56-0
Fax: +49 (0) 735156-1488
www.kavo.com

3. Material : See dedicated section "Components"

4. Sterilization: The product is NO STERILE.

Method of sterilization: steam (according to indication in IFU see Annex 01)

Information about the sterilization process validation in Annex 04

5. Packaging

Products are packaged in specific envelope for steam sterilization

	First packaging	Second packaging	Final packaging	Pallet 120x80
No pcs	1	2	22	880
Box /envelope	Plastic/paper envelope Medical paper 60 gr/m ² - Plastic film PET12/PP40 PEEL	White box 25x30x4h cm + N° 1 copy of the IFU	Box 37,5x28x41h cm	/

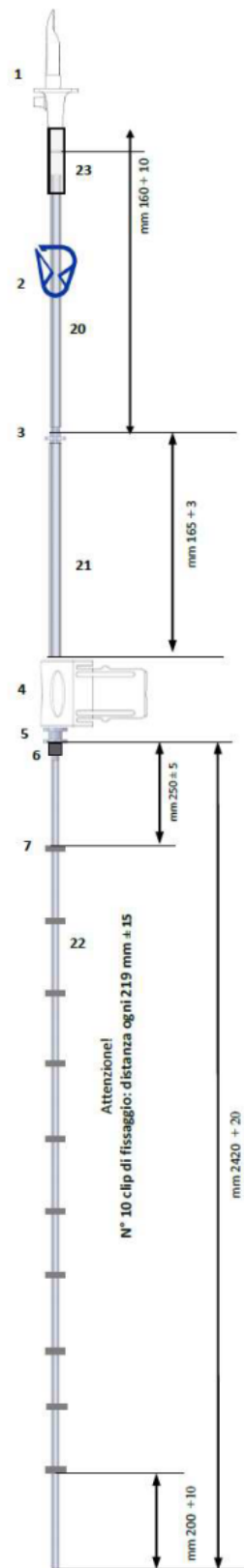
6. TECHNICAL DRAWING

1.011.0633
(30.F0341)

Components - Technical description:

(see section "Components" for all technical data)

1	2 ways vented spike - PC and ABS
2	Clamp - PP
3	Connector - POM
4	Plastic Key - POM
5	Connector for pump tube - APEC1745 (Bayer) transparent
6	Stainless steel ring
7	Fixing clips - ULTRASON (BASF)
20	Irrigation tube Silicone 60 ShA Ø mm 3x4,1 - 165 mm
21	Tube for peristaltic pump Silicone 50 ShA - Ø mm 4x7 - 190 mm
22	Irrigation tube Silicone 60 ShA Ø mm 1x3 - 2420 mm
23	Tube Silicone 60 ShA Ø mm 4x7 - 30 mm



OMNIA Spa—Via F. Delnevo 190—43036 Fidenza (PR)

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7. LABELING

In Annex 01 :

LABEL FOR FIRST PACKAGING - 1 PC
Label real dimensions 10 x 15 cm

LABEL FOR SECONDARY PACKAGING - 2 PCS
Label real dimensions 10 x 15 cm

LABEL FOR FINAL PACKAGING - 22 PC
Label real dimensions 10 x 15 cm

8. INSTRUCTION FOR USE :

In Annex 01 : IFU with all specification and information according to ISO 17664

COMPONENTS

In Annex 02 :

all details of components in point 6 - drawings and technical data sheets of the materials

COMPONENTS FOR PACKAGING

In Annex 03 :

all details of envelope - drawing and technical data sheet

*Envelope for steam sterilization
(Medical paper 60 gr/m² - Plastic film PET12/PP40)
20X30 cm*



10.06.2015 - Annex 1



ANNEX 1

LABELS and IFU

First packaging	Plastic/paper envelope 20 x 30 cm Medical paper 60 gr/m ² - Plastic film PET12/PP40 PEEL Label 10 x 15 cm
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Barcode construction

	LIC	Ref.	Packaging level		Q.ty field		Lot field		Check digit	
BLISTER (1 PC)	+EFID	1.011.0633	0	/\$\$	8		7	<assigned> e.g. 123456	<calculated> 1	
BOX (2 PCS)			1						02	<calculated> 3
CARTON (22 PCS)			2						22	<calculated> 6

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Sterilisierbares Schlauchset S600
Sterilizable Hose Set S600

Catalog number NOT MADE WITH NATURAL RUBBER LATEX
REF 1.011.0633 PHTHALATES FREE

Lot number
LOT

Date of manufacture


 Manufacturer: OMNIA Spa
www.omniaspa.eu **CE** 0546

Consult instruction for use


Keep away from sunlight


Keep dry


Do not use if package is damaged

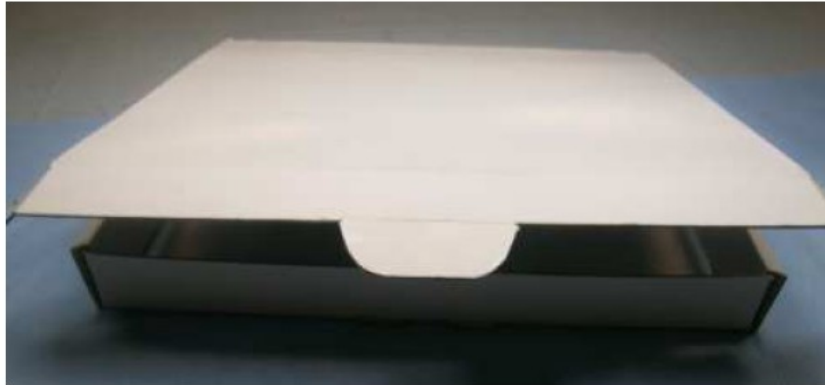

Non-sterile




! Caution: US Federal law restricts this device to sale by or on the order of a health care professional/dentist. For dental use only.

Rev. 01/2015

Second packaging	Carton box - white - 25x30x4h cm - 2 pc + IFU Label 10 x 15 cm
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Sterilisierbares Schlauchset S600
Sterilizable Hose Set S600
BOX =2 PCS

NOT MADE WITH NATURAL RUBBER LATEX
PHTHALATES FREE



Catalog number
REF 1.011.0633

Lot number
LOT

Date of manufacture


Manufacturer:
OMNIA Spa
www.omniaspa.eu

CE 0546

Consult instruction for use 

Keep away from sunlight 

Keep dry 

Do not use if package is damaged 

Non-sterile 

Caution: US Federal law restricts this device to sale by or on the order of a health care professional/dentist. For dental use only.

Rev. 01/2015

Final packaging	Carton box – white – 37,5x28x41h cm – 22 pc Label 10 x 15 cm
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Sterilisierbares Schlauchset S600

Sterilizable Hose Set S600

11 BOX =22 PCS

NOT MADE WITH NATURAL RUBBER LATEX
PHTHALATES FREE



Catalog number
REF 1.011.0633

Lot number
LOT

Date of manufacture


Manufacturer:
OMNIA Spa
www.omniaspa.eu

CE 0546

Consult instruction for use


Keep away from sunlight


Keep dry


Do not use if package is damaged


Non-sterile

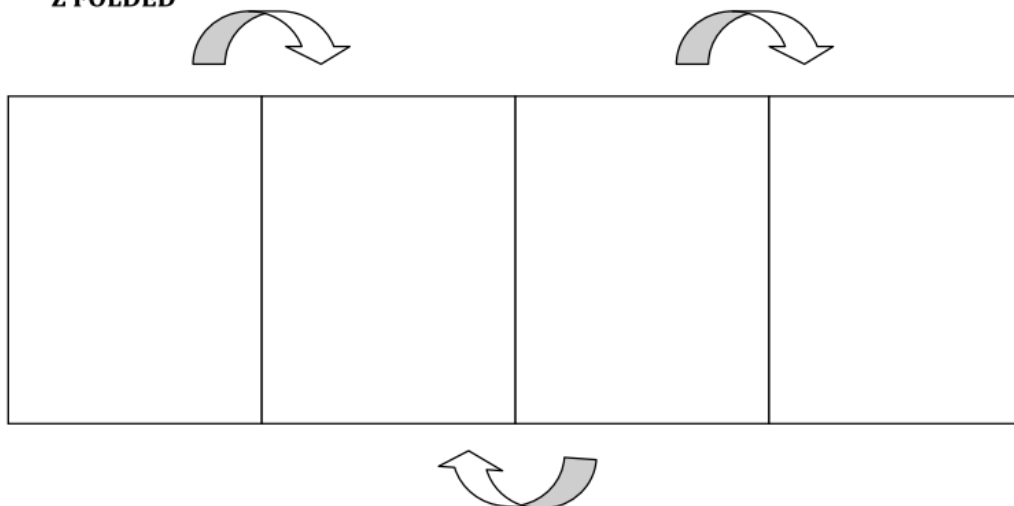

! Caution: US Federal law restricts this device to sale by or on the order of a health care professional/dentist. For dental use only.

Rev. 01/2015

IFU – 80.M0050 – REV00/APRILE/2015

- **Paper 60 gr A5 format**
- **7 languages**
 - **Italian**
 - **English**
 - **German**
 - **Russian**
 - **Japan**
 - **Chinese**
 - **Spanish**

Z FOLDED



<p>ПРИГОДНЫЙ ДЛЯ СТЕРИЛИЗАЦИИ КОМПЛЕКТ ШЛАНГОВ S600 Использование: — для стерилизации</p> <p>УКАЗАНИЕ НАЗНАЧЕНИЕ ПРОДУКТА. Продукт предназначен для стерилизации шлангов S600 для использования в стоматологии, ортодонтии и в области неинвазивной хирургии.</p> <p>ПРЕДУПРЕЖДЕНИЕ В целях обеспечения долговечности изделия следует избегать контакта с острыми предметами, канюльками и иглами. Избегайте контакта с агрессивными жидкостями, такими как отбеливатель, перекись водорода и спирт.</p> <p>Данное изделие не следует использовать только с медицинскими изделиями, предназначенными для данного конкретного изделия.</p> <p>Данное изделие не следует использовать в системах «НЕ СТЕРИЛИЗУЕМЫЕ». После использования изделие следует стерилизовать в течение 15 минут при 121 °C, а затем стерилизовать в течение 15 минут при температуре кипения в течение 15 минут.</p> <p>ОГРАНИЧЕНИЯ ПРИ ПОЛИМЕРИЗАЦИИ СВАДЕЖКИ Застывание стоматологического материала, например, в течение 15 минут после использования изделия может привести к повреждению изделия.</p> <p>Компания не гарантирует никаких гарантий по поводу размера, количества или качества изделия или его прочности, и не несет ответственности за любые повреждения, нанесенные или нанесенные в результате использования или неправильного использования продукта.</p> <p>УКАЗАНИЯ ОТНОСИТЕЛЬНО СТЕРИЛИЗАЦИИ ПРЕДУПРЕЖДЕНИЯ ЗАМЕЧАНИЕ: Рекомендуется избегать стерилизации медицинского изделия (при условии его использования).</p> <p>ПОДГОТОВКА К СТЕРИЛИЗАЦИИ Рабочий должен прочитать инструкции.</p> <p>СРЕДСТВА: Используйте латексные перчатки, а также защитные очки и маску при работе с изделием.</p> <p>ВНИМАНИЕ: Избегать контакта с острыми предметами и иглами. При контакте с агрессивными жидкостями, такими как отбеливатель, перекись водорода и спирт, немедленно промойте изделие проточной водой. Промывание проводится до тех пор, пока изделие не будет полностью очищено.</p> <p>СУШКА: Сухой продукт можно использовать сразу же после стерилизации при температуре не выше 121 °C.</p> <p>ТЕХНИЧЕСКИЕ ОСОБЕННОСТИ, СВОЙСТВА И ПРОЦЕДУРЫ На изделие не должно быть никаких изменений, не должно быть повреждений, утечек или деформаций. Если обнаружены повреждения, изделие не следует использовать.</p> <p>УПАКОВКА: Для сохранения стерильности изделие в упаковке должно быть закрыто.</p> <p>СТЕРИЛИЗАЦИЯ: Выполните стерилизацию в течение 15 минут при 121 °C в автоклаве (тип B). Внимание: НЕ ДОПУСКАЙТЕ ПОСЛЕДСТВИЙ НЕПРАВИЛЬНОГО РАБОТЫ УПАКОВКИ ИЛИ НЕПРАВИЛЬНОГО РАБОТЫ С ШЛАНГОМ ПО СЛАНГОВОМУ СИСТЕМЕ.</p> <p>Внимание: Избегать контакта с агрессивными жидкостями, такими как отбеливатель, перекись водорода и спирт.</p> <p>ДОПОЛНИТЕЛЬНЫЕ ИНФОРМАЦИИ Пожалуйста, внимательно прочтите инструкцию по эксплуатации изделия. Внимание: Не использовать изделие, если упаковка повреждена.</p>	<p>STERILISIERBARES SCHLAUCHSET S600 Anwendung: — für die Sterilisation</p> <p>WICHTIG Zweckbestimmung: Das Produkt ist für die Sterilisation von S600-Schläuchen für den Einsatz in der Zahnmedizin, Orthodontie und in der nicht-invasiven Chirurgie vorgesehen.</p> <p>VORSICHT Um die Lebensdauer des Produkts zu gewährleisten, vermeiden Sie Kontakt mit scharfen Gegenständen, Kanülen und Nadeln. Vermeiden Sie Kontakt mit aggressiven Flüssigkeiten wie Bleichmittel, Wasserstoffperoxid und Alkohol.</p> <p>Dieses Produkt ist nicht für den Einsatz mit nur für dieses Produkt vorgesehenen medizinischen Geräten zu verwenden.</p> <p>Dieses Produkt ist nicht für den Einsatz in „Nicht-sterilisierten“-Systemen zu verwenden. Nach dem Gebrauch sollte das Produkt für 15 Minuten bei 121 °C und anschließend für 15 Minuten bei Siedetemperatur für 15 Minuten sterilisiert werden.</p> <p>BEWEGUNGSGRENZEN BEI DER POLYMERISATION VON ZAHNKLÄMMEN Die Aushärtung des Zahntechniker-Materials, z. B. innerhalb von 15 Minuten nach dem Gebrauch des Produkts, kann zu Beschädigungen des Produkts führen.</p> <p>Das Unternehmen garantiert keine Garantien hinsichtlich der Größe, der Menge oder der Qualität des Produkts, und es übernimmt keine Haftung für Schäden, die durch die Verwendung oder die falsche Verwendung des Produkts entstehen.</p> <p>ANLEITUNG ZUR STERILISATION VORSICHTSMAßNAHMEN: Es wird empfohlen, die Sterilisation von medizinischen Geräten (falls zutreffend) zu vermeiden.</p> <p>VORBEREITUNG: Bitte lesen Sie die Anweisungen.</p> <p>Werkzeuge: Verwenden Sie Latexhandschuhe, eine Schutzbrille und eine Maske bei der Arbeit mit dem Produkt.</p> <p>WICHTIG: Vermeiden Sie Kontakt mit scharfen Gegenständen und Nadeln. Bei Kontakt mit aggressiven Flüssigkeiten wie Bleichmittel, Wasserstoffperoxid und Alkohol, spülen Sie das Produkt sofort gründlich mit Wasser ab. Spülen Sie das Produkt bis es vollständig sauber ist.</p> <p>Trocknen: Das sterilisierte Produkt kann sofort verwendet werden, wenn die Sterilisation bei einer Temperatur von nicht mehr als 121 °C erfolgt.</p> <p>TECHNISCHE EIGENSCHAFTEN, EIGENSCHAFTEN UND VERFAHREN Das Produkt darf nicht verändert werden, es dürfen keine Beschädigungen, Lecks oder Verformungen festgestellt werden. Wenn Beschädigungen festgestellt werden, darf das Produkt nicht verwendet werden.</p> <p>PACKUNG: Um die Sterilität des Produkts zu gewährleisten, muss die Verpackung nach dem Gebrauch geschlossen sein.</p> <p>STERILISATION: Sterilisieren Sie das Produkt für 15 Minuten bei 121 °C in einem Autoklav (Typ B). Wichtig: VERMEIDEN SIE FOLGENDES: FALSCHES VERFAHREN DER VERPACKUNG ODER FALSCHES VERFAHREN MIT DEM SCHLAUCHSYSTEM.</p> <p>Wichtig: Vermeiden Sie Kontakt mit aggressiven Flüssigkeiten wie Bleichmittel, Wasserstoffperoxid und Alkohol.</p> <p>ZUSÄTZLICHE INFORMATIONEN Bitte lesen Sie die Bedienungsanleitung des Produkts.</p>	<p>STERILISABLE HOSE SET S600 Use only for the sterilisation of dental hoses.</p> <p>WARNING The product may only be used with persons qualified in oral, orthodontic and dental medicine (e.g. dentists, dental assistants).</p> <p>The product may only be used with basic parts which are suitable for the hose set.</p> <p>The product is not to be used in a „NON-STERILE“ condition. Therefore for 15 min. at 121 °C in the autoclave type B. The material must be autoclaved with indication of 121 °C for 15 min.</p> <p>LIMITATIONS ON REPROCESSING Do not reuse and/or reprocess the product more than 25 times. Longer use could endanger the functionality.</p> <p>The company disclaims any liability for injury to patients and/or personnel carrying out treatment if the product is used in a damaged, changed or wrong way or when it is used for purposes other than its intended purpose.</p> <p>INSTRUCTIONS FOR THE STERILIZATION PRELIMINARY NOTE: It is recommended to avoid sterilisation of the product alongside other items.</p> <p>PREPARATION FOR CLEANING: The product is not intended to be disassembled.</p> <p>CLEANING: Rinse the product through the tubes for approx. 2 minutes with the hose open. Attention: make sure that the water surface of the product is clean. If this is not the case, wipe the surface with disinfectant. Check and replace the hose set on the surface after a separate hose.</p> <p>DRYING: There are no special requirements, but avoid the temperature of 121 °C if you use a dryer.</p> <p>STORAGE, PACKAGING AND TESTS: The hose set for each delivery unit has an individual seal (broken parts – no specific technical tests are required).</p> <p>STERILIZATION: Pack the product individually in bags for the steam sterilisation. Attention: make sure that the sterilisation process of your machine is suitable for the product type.</p> <p>STORAGE: 15 min. at 121 °C in the autoclave (type B). Attention: NO contact with other products! Keep the bag away from the walls of the pressure vessel. Attention: make sure that the sterilisation process of your machine is suitable for the product type.</p> <p>ADDITIONAL INFORMATION: Do not reuse and/or reprocess the product. Attention: Do not use the product if the packaging is damaged.</p>	<p>JUEGO DE MANGUERAS ESTERILIZABLES S600 Solo para uso de esterilización</p> <p>INDICACIONES DESIGNACIÓN DEL PRODUCTO Juego de mangueras esterilizables S600 para uso dental, local y móvil.</p> <p>ADVERTENCIA El producto solo debe utilizarse con equipos personal cualificado en odontología, ortodoncia y cirugía no invasiva.</p> <p>El producto solo debe utilizarse con partes básicas adecuadas para el juego de mangueras.</p> <p>El producto no debe utilizarse en estado „NO ESTÉRIL“. Antes de utilizarlo, esterilizar el producto durante 15 minutos a 121 °C en un autoclave tipo B. La superficie del material debe guardarse también con una temperatura de 121 °C durante 15 minutos.</p> <p>LIMITACIONES EN LA REPROCESADO No volver a utilizar ni reprocesar el producto más de 25 veces. Un uso prolongado puede comprometer la funcionalidad del juego de mangueras.</p> <p>La compañía no se responsabiliza de lesiones a pacientes y/o personal que realice el tratamiento si el producto se utiliza de una manera incorrecta, cambiada o equivocada o cuando se utiliza para fines distintos a los previstos.</p> <p>INDICACIONES PARA LA ESTERILIZACIÓN PRELIMINAR: Se recomienda evitar la esterilización del producto mezclándolo con otros.</p> <p>PREPARACIÓN PARA LA LIMPIEZA: No desmontar el producto.</p> <p>LIMPIEZA: Enjuague el juego de mangueras durante unos minutos con el agua destilada con el juego de mangueras abierto. Atención: asegure de que la superficie exterior del producto es limpia. Si no es así, limpie la superficie con desinfectante. Compruebe y reemplace el juego de mangueras en la superficie después de un juego de mangueras separado.</p> <p>SECAJE: No hay requisitos especiales, pero evite la temperatura de 121 °C si utiliza un secador.</p> <p>ALMACENAMIENTO Y ENSAYOS: El producto debe estar en condiciones de uso de esterilización personal (dentado local o móvil). Atención: NO debe haber contacto con otros productos. Mantenga la bolsa de los juegos de mangueras lejos de las paredes del recipiente de presión.</p> <p>ESTERILIZACIÓN: 15 minutos a 121 °C en un autoclave (tipo B). Atención: NO debe haber contacto con otros productos. Mantenga la bolsa de los juegos de mangueras lejos de las paredes del recipiente de presión.</p> <p>ADICIONALES INFORMACIONES: No volver a utilizar ni reprocesar el producto. Atención: No utilizar el producto si el embalaje está dañado.</p>
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<p>LINEA DI IRRIGAZIONE STERILIZZABILE S600 Solo para uso de esterilización</p> <p>ISTRUZIONI DESIGNAZIONE DEL PRODOTTO Linea di irrigazione sterilizzabile S600 per uso odontologico e mobile locale.</p> <p>AVVERTENZE Il prodotto medico deve essere utilizzato solo da personale qualificato in odontologia (es. medici, igienisti dentali).</p> <p>Il prodotto medico deve essere utilizzato solo con parti per le quali è idoneo alla linea di irrigazione.</p> <p>Il prodotto non deve essere utilizzato in condizioni „NON STERILI“. Prima dell'uso, sterilizzare il prodotto durante 15 minuti a 121 °C in un autoclave tipo B. La superficie del materiale deve essere conservata anche con una temperatura di 121 °C per 15 minuti.</p> <p>LIMITAZIONI DEL REPROCESSO Non usare e/o reprocessare il prodotto più di 25 volte. Un utilizzo prolungato comprometterà la funzionalità dell'intero sistema di irrigazione.</p> <p>La compagnia non si assume alcuna responsabilità per danni a pazienti e/o al personale sanitario, qualora il prodotto viene utilizzato in modo improprio, riprocessato o quando è utilizzato per scopi non previsti.</p> <p>ISTRUZIONI PER LA STERILIZZAZIONE PRELIMINARE: Si raccomanda di evitare di sterilizzare il prodotto in presenza di altri prodotti, non appena possibile.</p> <p>PREPARAZIONE PER LA PULIZIA: Non smontare il prodotto.</p> <p>PULIZIA: Rinviare con acqua per circa 2 minuti l'acqua acidificata all'interno del sistema mediante attivazione della pompa peristaltica.</p> <p>Attenzione: assicurarsi che la superficie esterna del dispositivo sia pulita in caso contrario, sciacquare con acqua pulita. Controllare e sostituire il sistema di irrigazione dopo un uso prolungato del gruppo di irrigazione.</p> <p>SECCAZIONE: Non utilizzare il prodotto se non è stato sterilizzato a una temperatura di 121 °C.</p> <p>ALMACENAMENTO, ESAMI E PROVA: La linea deve essere mantenuta in condizioni di uso di sterilizzazione personale (dentale locale o mobile).</p> <p>COMPENDIAMENTO: Confermare il corretto impiego del prodotto in base alle indicazioni alla sterilizzazione e al trasporto.</p> <p>Attenzione: NON deve aver contatto con altri prodotti! Mantenere la borsa (contiene) lontano dalle pareti del recipiente di pressione.</p> <p>ESTERILIZZAZIONE: Sterilizzare il prodotto in autoclave (tipo B) a 121 °C per 15 minuti.</p> <p>Attenzione: NON deve aver contatto con altri prodotti! Mantenere la borsa (contiene) lontano dalle pareti del recipiente di pressione.</p> <p>ADICIONALES INFORMACIONES: No volver a utilizar ni reprocesar el producto. Atención: No utilizar el producto si el embalaje está dañado.</p>	<p>STERILISIERBARES SCHLAUCHSET S600 Anwendung: — für die Sterilisation</p> <p>WICHTIG Zweckbestimmung: Das Produkt ist für die Sterilisation von S600-Schläuchen für den Einsatz in der Zahnmedizin, Orthodontie und in der nicht-invasiven Chirurgie vorgesehen.</p> <p>VORSICHT Um die Lebensdauer des Produkts zu gewährleisten, vermeiden Sie Kontakt mit scharfen Gegenständen, Kanülen und Nadeln. Vermeiden Sie Kontakt mit aggressiven Flüssigkeiten wie Bleichmittel, Wasserstoffperoxid und Alkohol.</p> <p>Dieses Produkt ist nicht für den Einsatz mit nur für dieses Produkt vorgesehenen medizinischen Geräten zu verwenden.</p> <p>Dieses Produkt ist nicht für den Einsatz in „Nicht-sterilisierten“-Systemen zu verwenden. Nach dem Gebrauch sollte das Produkt für 15 Minuten bei 121 °C, a dann sterilisiert werden in einem Autoklav (Typ B). Die Oberfläche des Materials muss ebenfalls mit einer Temperatur von 121 °C für 15 Minuten aufbewahrt werden.</p> <p>BEWEGUNGSGRENZEN BEI DER POLYMERISATION VON ZAHNKLÄMMEN Die Aushärtung des Zahntechniker-Materials, z. B. innerhalb von 15 Minuten nach dem Gebrauch des Produkts, kann zu Beschädigungen des Produkts führen.</p> <p>Das Unternehmen garantiert keine Garantien hinsichtlich der Größe, der Menge oder der Qualität des Produkts, und es übernimmt keine Haftung für Schäden, die durch die Verwendung oder die falsche Verwendung des Produkts entstehen.</p> <p>ANLEITUNG ZUR STERILISATION VORSICHTSMAßNAHMEN: Es wird empfohlen, die Sterilisation von medizinischen Geräten (falls zutreffend) zu vermeiden.</p> <p>VORBEREITUNG: Bitte lesen Sie die Anweisungen.</p> <p>Werkzeuge: Verwenden Sie Latexhandschuhe, eine Schutzbrille und eine Maske bei der Arbeit mit dem Produkt.</p> <p>WICHTIG: Vermeiden Sie Kontakt mit scharfen Gegenständen und Nadeln. Bei Kontakt mit aggressiven Flüssigkeiten wie Bleichmittel, Wasserstoffperoxid und Alkohol, spülen Sie das Produkt sofort gründlich mit Wasser ab. Spülen Sie das Produkt bis es vollständig sauber ist.</p> <p>Trocknen: Das sterilisierte Produkt kann sofort verwendet werden, wenn die Sterilisation bei einer Temperatur von nicht mehr als 121 °C erfolgt.</p> <p>TECHNISCHE EIGENSCHAFTEN, EIGENSCHAFTEN UND VERFAHREN Das Produkt darf nicht verändert werden, es dürfen keine Beschädigungen, Lecks oder Verformungen festgestellt werden. Wenn Beschädigungen festgestellt werden, darf das Produkt nicht verwendet werden.</p> <p>PACKUNG: Um die Sterilität des Produkts zu gewährleisten, muss die Verpackung nach dem Gebrauch geschlossen sein.</p> <p>STERILISATION: Sterilisieren Sie das Produkt für 15 Minuten bei 121 °C in einem Autoklav (Typ B). Wichtig: VERMEIDEN SIE FOLGENDES: FALSCHES VERFAHREN DER VERPACKUNG ODER FALSCHES VERFAHREN MIT DEM SCHLAUCHSYSTEM.</p> <p>Wichtig: Vermeiden Sie Kontakt mit aggressiven Flüssigkeiten wie Bleichmittel, Wasserstoffperoxid und Alkohol.</p> <p>ZUSÄTZLICHE INFORMATIONEN Bitte lesen Sie die Bedienungsanleitung des Produkts.</p>	<p>STERILISABLE HOSE SET S600 Use only for the sterilisation of dental hoses.</p> <p>WARNING The product may only be used with persons qualified in oral, orthodontic and dental medicine (e.g. dentists, dental assistants).</p> <p>The product may only be used with basic parts which are suitable for the hose set.</p> <p>The product is not to be used in a „NON-STERILE“ condition. Therefore for 15 min. at 121 °C in the autoclave type B. The surface of the material must also be stored with a temperature of 121 °C for 15 minutes.</p> <p>LIMITATIONS ON REPROCESSING Do not reuse and/or reprocess the product more than 25 times. Longer use could endanger the functionality.</p> <p>The company disclaims any liability for injury to patients and/or personnel carrying out treatment if the product is used in a damaged, changed or wrong way or when it is used for purposes other than its intended purpose.</p> <p>INSTRUCTIONS FOR THE STERILIZATION PRELIMINARY NOTE: It is recommended to avoid sterilisation of the product alongside other items.</p> <p>PREPARATION FOR CLEANING: The product is not intended to be disassembled.</p> <p>CLEANING: Rinse the product through the tubes for approx. 2 minutes with the hose open. Attention: make sure that the water surface of the product is clean. If this is not the case, wipe the surface with disinfectant. Check and replace the hose set on the surface after a separate hose.</p> <p>DRYING: There are no special requirements, but avoid the temperature of 121 °C if you use a dryer.</p> <p>STORAGE, PACKAGING AND TESTS: The hose set for each delivery unit has an individual seal (broken parts – no specific technical tests are required).</p> <p>STERILIZATION: Pack the product individually in bags for the steam sterilisation. Attention: make sure that the sterilisation process of your machine is suitable for the product type.</p> <p>STORAGE: 15 min. at 121 °C in the autoclave (type B). Attention: NO contact with other products! Keep the bag away from the walls of the pressure vessel. Attention: make sure that the sterilisation process of your machine is suitable for the product type.</p> <p>ADDITIONAL INFORMATION: Do not reuse and/or reprocess the product. Attention: Do not use the product if the packaging is damaged.</p>	<p>JUEGO DE MANGUERAS ESTERILIZABLES S600 Solo para uso de esterilización</p> <p>INDICACIONES DESIGNACIÓN DEL PRODUCTO Juego de mangueras esterilizables S600 para uso dental, local y móvil.</p> <p>ADVERTENCIA El producto solo debe utilizarse con equipos personal cualificado en odontología (es. médicos, higienistas dentales).</p> <p>El producto solo debe utilizarse con partes básicas adecuadas para el juego de mangueras.</p> <p>El producto no debe utilizarse en estado „NO ESTÉRIL“. Antes de utilizarlo, esterilizar el producto durante 15 minutos a 121 °C en un autoclave tipo B. La superficie del material debe guardarse también con una temperatura de 121 °C durante 15 minutos.</p> <p>LIMITACIONES EN LA REPROCESADO No volver a utilizar ni reprocesar el producto más de 25 veces. Un uso prolongado comprometerá la funcionalidad del sistema de irrigación.</p> <p>La compañía no se responsabiliza de lesiones a pacientes y/o personal que realice el tratamiento si el producto se utiliza de una manera incorrecta, cambiada o equivocada o cuando se utiliza para fines distintos a los previstos.</p> <p>INDICACIONES PARA LA ESTERILIZACIÓN PRELIMINAR: Se recomienda evitar la esterilización del producto mezclándolo con otros.</p> <p>PREPARACIÓN PARA LA LIMPIEZA: No desmontar el producto.</p> <p>LIMPIEZA: Enjuague el juego de mangueras durante unos minutos con agua destilada con el juego de mangueras abierto. Atención: asegure de que la superficie exterior del producto es limpia. Si no es así, limpie la superficie con desinfectante. Compruebe y reemplace el juego de mangueras en la superficie después de un juego de mangueras separado.</p> <p>SECAJE: No hay requisitos especiales, pero evite la temperatura de 121 °C si utiliza un secador.</p> <p>ALMACENAMIENTO Y ENSAYOS: El producto debe estar en condiciones de uso de esterilización personal (dentado local o móvil). Atención: NO debe haber contacto con otros productos. Mantenga la bolsa de los juegos de mangueras lejos de las paredes del recipiente de presión.</p> <p>ESTERILIZACIÓN: 15 minutos a 121 °C en un autoclave (tipo B). Atención: NO debe haber contacto con otros productos. Mantenga la bolsa de los juegos de mangueras lejos de las paredes del recipiente de presión.</p> <p>ADICIONALES INFORMACIONES: No volver a utilizar ni reprocesar el producto. Atención: No utilizar el producto si el embalaje está dañado.</p>
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10.06.2015 - Annex 2



ANNEX 2

COMPONENTS

COMPONENT 1 : 2 WAYS VENTED SPIKE—PC and ABS

PHYSICAL FEATURES	NORMS	TYPICAL VALUE	MEASURE UNITS
1) Specific weight	ISO 1183	1.2	Kg/dm ³
2) Hardness	ASTM D-2240	D/81±3	SHORE
3) Tensile strength	ISO 527	63 at yield	MPa
4) Elongation	ISO 527	6 at yield	%
5) Thermal coefficient of linear expansion	ASTM E-831	0.7	10 ⁻⁴ /K
6) Stiffness in torsion			
7) Vicat softening point			
STABILIZER(S)	:		
PLASTICIZER(S)	:		
COMPLIANCE	:	-Meets the requirements of: U.S.P. XXIII Ed. - Class VI - Plastics	
MAJOR USE	:	Extrusion <input type="checkbox"/>	
	:	Moulding <input checked="" type="checkbox"/>	
	:	Blowing <input type="checkbox"/>	
PACKAGING	:	Goods delivered in polyethylene or paper bags weighing 25 kg each or 600-800 kg	
ASPECT	:	Plastic granules	Colourless <input checked="" type="checkbox"/>
			Red <input type="checkbox"/>
			Blue <input type="checkbox"/>
			White <input type="checkbox"/>
STORAGE CONDITIONS	:	Maintain containers closed in a clean and well-aired environment. Avoid direct light and excessive humidity.	
STERILIZATION TYPE	:	Ethylene oxide <input checked="" type="checkbox"/>	
		Gamma radiation <input type="checkbox"/>	
		Steam <input checked="" type="checkbox"/>	
NOTES	:	-This material can be used for components which come into contact with blood and/or "solutions".	



COMPONENT 2: CLAMP —PP



Product Data and Technical Information

[✉ Email this page](#) [🖨 Print this page](#)

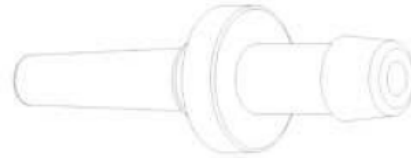
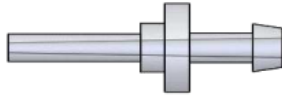
Name Moplen

Grade HP501H

Resin type Polypropylene, Homopolymer

Description *Moplen* HP501H is a homopolymer for injection moulding which exhibits a good stiffness/impact balance at ambient temperatures. The main applications of *Moplen* HP501H are caps, closures and furniture. *Moplen* HP501H is suitable for food contact.

COMPONENT 3 : CONNECTOR FOR PUMP TUBE —POM

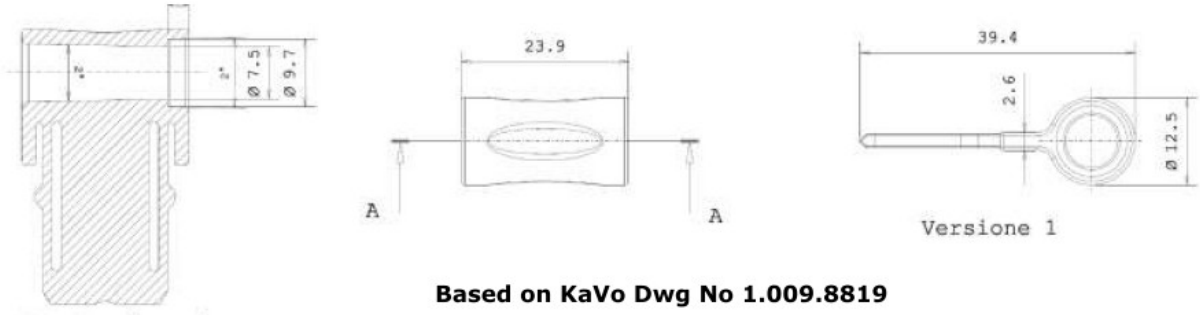


KOCETAL[®] K300

Kocetal K300 is a general injection molding grade with a good mechanical property for wide range.

Property	Test Method	Units	Value
Physical			
Melt Index	ASTM D1238	g/10min	9.0
Specific Gravity	ASTM D792	-	1.41
Shrinkage	ASTM D955	%	2.0
Water Absorption 23°C Equilibrium 60%RH	ASTM D570	%	0.22
Thermal			
Melting Point	ASTM D1525	°C	166
Heat Deflection Temperature under Load			
HDT/A 0.45 MPa (4.6 kg/cm ²)	ASTM D648	°C	158
HDT/A 1.82 MPa (18.6 kg/cm ²)		°C	110
Vicat Softening Temperature	ASTM D1525	°C	162
Coeff. Of Linear Thermal Expansion	ASTM D696	× 10 ⁻⁵ cm/cm·°C	13
Flammability	UL 94		HB
Mechanical			
Tensile Strength 23°C	ASTM D638	MPa (kg/cm ²)	64 (650)
Tensile Elongation 23°C	ASTM D638	%	60
Flexural Strength 23°C	ASTM D790	MPa (kg/cm ²)	94 (960)
Flexural Modulus 23°C	ASTM D790	MPa (kg/cm ²)	2,500 (25,500)
Notched Izod Impact Strength 23°C	ASTM D256	J/m (kg-cm/cm)	67 (6.8)
Rockwell Hardness M scale	ASTM D785	-	80
Electrical			
Surface Resistivity	ASTM D257	× 10 ¹⁶ Ω	1
Volume Resistivity	ASTM D257	× 10 ¹⁴ Ω-cm	1
Dielectric Strength	ASTM D149	kV/mm	19
Dielectric Constant	ASTM D150	-	3.7
Dielectric Dissipation FactorConstan 10 ⁶ Hz	ASTM D150	-	0.006

COMPONENT 4 : PLASTIC KEY —POM - Color: white RAL 9016



Based on KaVo Dwg No 1.009.8819

Certification

Company : **KOLONPLASTICS, Inc.**
 Address : **1018 Ungmyung-Dong, Gimchon-Si, GyungSangBuk-Do, 740-180, Korea**
 Name and the function :

We certify the co-polymers, **POM KOCETAL® K300; 1,3,5-Trioxane, polymer with 1,3-dioxolane, Cas No.24969-26-4 (submitter names) : copolymer of dioxolane and trioxane** , supplied by **KOLONPLASTICS, Inc. does not contain Environmentally Hazardous Substances mentioned category.**

- **Materials for Certification**
POM KOCETAL® K300

- **Category**
**PARABENS
 PHTHALATE
 alkylphenols**

13 July 2011
 Date

R&D Division
 KOLONPLASTICS, Inc.
 Tel: +82-54-420-8472
 Fax: +82-54-420-8329

Approved by 
Jong-Mun Kim / R&D Division Manager
 Signature & Supplier's stamp

COMPONENT 5 : CONNECTOR



Apec 1745

Standard grades / Medical applications, suitable for superheated steam sterilization

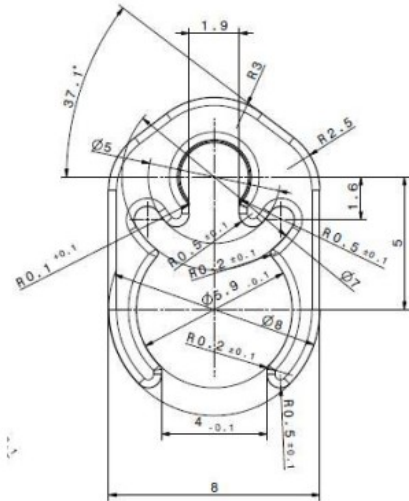
Easy to demold, suitable for superheated steam sterilisation up to 143 °C as well as for pharmaceutical applications according to United States Pharmacopeia (USP) XXII Class VI, softening temperature (VST/B 120)=170 °C

COMPONENT 6 : STAINLESS STEEL RING



COMPONENT 7 : FIXING CLIPS —ULTRASON (BASF) – PSU- TRANSPARENT

Based on KaVo Dwg No 1.009.8818



Product Information

July 2004

**Ultrason[®] S 2010 natural
(PSU)**

BASF
The Chemical Company

Product description

Unreinforced, medium viscosity standard injection moulding grade.
Abbreviated designation according to ISO 1043-1: PSU

COMPONENT 20 : SILICONE 60 ShA - 3 x 4,1—L 16,5 cm
COMPONENT 22 : SILICONE 60 ShA - 1 x 3 — L 242 cm
COMPONENT 23 : SILICONE 60 ShA - 4 x 7 —L 3 cm

Nome Prodotto RESIL-60/T		Colorabile	
Elastomero di Base : Gomma Siliconica			
Prove eseguite su : trafilato			
Caratteristiche	Metode	Nostra Mescola	
Peso specifico	UNI 7092-A	g/cm ³	1,180 +/- 0,020
Durezza	UNI 4916	SHORE A	60 +/- 5
Carico di Rottura	UNI 6065	MPa	8 min
Allungamento a Rottura	UNI 6065	%	300 min
Resistenza alla Lacerazione	UNI 4914	KN/m	12 min
Compression Set			
Sch. 25X 175°C 22h.	UNI 4913/A	%	30 max
Resistenze chimiche e fisiche			
Resistenza a :			
IMPERMEABILITA' AI GAS		Insofficiente	
ARIA CALDA FINO A 180°C		Ottima	
AGENTI ATMOSFERICI		Ottima	
OZONO		Ottima	
IRRIGIDIMENTO BASSA TEMPERATURA		Ottima	
OLII MINERALI PARAFFINICI		Buona	
IDROCARBURI ALIFATICI		Insofficiente	
OLII ANIMALI E/O VEGETALI		Ottima	
IDROCARBURI AROMATICI		Insofficiente	
SOLVENTI CLORURATI		Insofficiente	
CHETONI		Sufficiente	
ACIDI		Sufficiente	
BASI		Sufficiente	
VAPORE		Insofficiente	
" Le valutazioni relative alle resistenze chimiche e fisiche si devono considerare indicazioni di massima: esse sono ricavate sia dalle caratteristiche intrinseche dell'elastomero di base, sia dalla natura chimica degli altri ingredienti presenti nella mescola con la quale è prodotto il manufatto. Comunque i dati vengono comunicati a titolo informativo e non impegnano la società POSA S.P.A.			
Temperatura d'impiego : Min. - 60°C Max. 180°C			

COMPONENT 21 : SILICONE 50 ShA - 4 x 7 —L 19 cm

Nome Prodotto : AXIL-50/T		Colorabile		
Elastomero di Base : VMQ				
Prove eseguite su piattine trafilate				
Compression set eseguito su dischi sovrapposti ricavati da lastrina stampata				
Caratteristiche	Metodo	Nostro Miscela		Valori Richiesti
Peso specifico	UNI ISO 1183-1 g/cm ³	1,140 +/-	0,020	
Durezza	UNI EM ISO 868 SHORE A	50,000 +/-	5,000	
Carico di Rettura	UNI 6065 MPa	8,000 min		
Allungamento a Rottura	UNI 6065 %	500,000 min		
Resistenza alla Lacerazione	ASTM D 624/B KN/m	28,000 min		
Compression Set				
Sch.25% 22h a 175°C	UNI ISO 815 %	25,000 max		
Resistenze chimiche e fisiche				
Resistenza a :				
ARIA CALDA FINO A 180°C		Ottima		
AGENTI ATMOSFERICI		Ottima		
OZONO		Ottima		
IRRIGIDIMENTO BASSA TEMPERATURA		Ottima		
IDROCARBURI ALIFATICI		Insufficiente		
OLII MINERALI PARAFFINICI		Buona		
OLII ANIMALI E/O VEGETALI		Ottima		
IDROCARBURI AROMATICI		Insufficiente		
SOLVENTI CLORURATI		Insufficiente		
CHETONI		Sufficiente		
ACIDI		Sufficiente		
BASI		Sufficiente		
VAPORE		Insufficiente		
Le valutazioni relative alle resistenze chimiche e fisiche si devono considerare indicazioni di massima: esse sono ricavate sia dalle caratteristiche intrinseche dell'elastomero di base, sia dalla natura chimica degli altri ingredienti presenti nella miscela con la quale è prodotto il manufatto. Comunque, i dati vengono comunicati a titolo informativo e non impegnano la società POSA SPA				
Temperatura d'Impiego : Min - 60°C Max 180°C				



10.06.2015 - Annex 3



ANNEX 3

COMPONENTS of PACKAGING

Envelope for steam sterilization (Medical paper 60 gr/m² - Plastic film PET12/PP40) – 20 x 30 cm

Property chemical-physical	Standards	Value	Unit of measure
PET 12μ			
Density	ASTM D1505	1,395 + 1,405	g/cm ³
COF static	ASTM D1894	< 0,6	/
COF kinetic	ASTM D1894	< 0,55	/
Point/fusion interval	/	260	°C
PP 40μ			
Density	Internal Method	0,9	g/m ³
COF	ASTM D1894	0,15 + 0,30	/
Point/fusion interval	/	150 + 170	°C
ADHESIVE			
Weight	/	1,6 – 2	g/m ²
<p>Test made in environmental conditions conform to Standard UNI EN ISO 11607-1:2006 (4.4.3). (23 ± 1) °C – (50 ± 2) % UR – 24 h, a part from different conditions indicated on the applied Standards.</p>			
CONFORMITY TO STANDARD	<p>Composite Film PET12/PP40 green is conform to Standard UNI EN ISO 11607:2006 and to Directive 94/62/CE of European Parliament and Council, , dtd December 20, 1994; on packaging and packaging' s waste.</p> <p>Conformity of the components to Standards applied:</p> <p>PET POLYETYLENE – UE: Commission Directive 2002/72/CE, 2004/19/CE, 2005/79/CE, 94/62/CE, 2002/16/CE, 2007/19/CE, Regulation 683/98, 1935/2004 and 1895/2005; Italy: Ministerial Decrees 21.3.1973 and DPR 777/82; USA: FDA, CFR, title 21 § 177.1500 (a) (6) e (b) (6.1-6.2) e CFR, title 21 § 177.1630</p> <p>PP POLYPROPYLENE – UE: Commission Directive 2002/72/CE; Italy: Ministerial Decrees 26.4.1993 n. 220, 28.10.1994 n. 735, 24.9.1996 n. 572, 6.2.1997 n. 91, 22.7.1998 n. 338, 15.6.2000 n. 210, and Ministerial Decrees 21.3.1973 n. 104, attach II, section I, part B; USA: FDA, CFR, title 21 (2002) § 177.1520 (a) (1), (b) and (c) 1.1</p> <p>ADHESIVE – UE: Commission Directive 2002/72/CE; Italy: Ministerial Decrees 21.3.1973; USA – FDA, CFR, title 21 § 175.105</p>		
DESCRIPTION MATERIAL	<p>Composite Film PET12/PP40 green is composed of a laminated Polyester and a laminate of Polypropylene. The adhesive interposes of two Films does not contain solvent, so the final product is solvent free.</p>		
APPLICATION	<p>Composite Film PET12/PP40 green is especially developed for single use medical application ; suggested for rotating or flat welding. Composite Film could be weld on itself and paper support. This material is suitable for <i>Steam</i> and EO (gas) sterilization.</p>		
TRACEABILITY	<p>The product/raw material is guaranteed through documentations keep by QC Encaplast's files for a period of 10 years.</p>		
GENERAL CONDITIONS OF STORAGE	<p>15-25°C 60% UR</p>		
 <p><i>It's responsibility of the user to validate the single packaging in accordance with Enclosure I Medical Directives Device 93/42/CEE, since product supplied by Encaplast is considered a component of Medical Device.</i></p>			
Property of ENCAPLAST Re-production strictly subject to authorization.			Drawer:  Date: 31-03-08 Variation N°: 256/08
	Responsible:  Date: 31-03-08 Date: 31-03-08		
	Description Composite Film PET 12 / PP 40 Green (Data Sheet)		
	Code: 2503350000	Rev. C	Pag. ___ of ___

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PROPERTY PHYSICAL-CHEMICAL	Standards	Typical Value	Unit of Measure
Paper Grammage	ISO 536	60	g/m ²
pH water extract	ISO 6588-2	7	/
Chloride content	ISO 9197	< 0.05	%
Sulphate content	ISO 9198	< 0.25	%
Burst strenght (dry)	ISO 2758	350	KPa
Burst strenght (wet)	ISO 3689	150	KPa
Traction strenght long. (dry)	ISO 1924-2	6,4	kN/m
Traction strenght transv.(dry)	ISO 1924-2	3,4	kN/m
Traction strenght long. (wet)	ISO 3781	2,1	kN/m
Traction strenght transv. (wet)	ISO 3781	1,1	kN/m
Tear strenght long.	ISO 1974	600	mN
Tear strenght transv.	ISO 1974	650	mN
Air permeability	ISO 5636-3	11,4	µm/(Pa.s)
Superficial roughness Bendtsen FS	ISO 8791-2	375	ml/mn
Superficial roughness Bendtsen WS	ISO 8791-2	300	ml/mn
Superficial absorption (Cobb)	EN 20535	15	g/m ²
Hydrophobia (water repellency)	ASTM D779-03	35	sec
Fluorescence	DfN 58953-6	0	%
Pore diameter	EN 868-2 (all. C)	21	µm

Test made in environmental conditions conform to standard UNI EN ISO 11607-1:2006 (4.4.3), (23 ± 1) °C – (50 ± 2) % UR – 24 h, unless different conditions indicated on specific standards applicated.

CONFORMITY TO STANDARDS Medical Paper HL 60g/m² is conform to standards :
UNI EN ISO 11607-1:2006, EN 868-3:1999, FDA CFR 21. BfR (B_gVV) XXXVI;
and is made in accordance to standard EN ISO 9001.

MATERIAL DESCRIPTION Medical Paper HL 60g/m² is humidity-resistance and have a degree of roughness that made it suitable to EO (gas) and Steam sterilization. It present high bacterial barrier. Is indicated as a support for flex graphic and rotogravure printing.

APPLICATION Medical Paper HL 60g/m² is especially indicated for the production of pouches and rolls, printing and unprinting, where the Paper is hot welding with composít film polyester/poliprophylene. This packaging can be used for EO (gas) and Steam sterilization. If is welding with polyester/polyethylene, is indicated for EO (gas) and Radiation.

TRACEABILITY Traceability of products/prime material is guaranteed throught registration documents held in CQ Encaplast file, for a period of 10 years.

GENERAL CONDITION OF STORAGE 15-25°C 60% UR



It's the responsibility to the user to validate the single packaging in accordance with the Enclosure 1 Medical Device Directives 93/42/CEE, since product supplied by Encaplast is considered a component of the Medical Device.

Property of ENCAPLAST Re-production strictly subject to authorization.		Drawer <i>Marchi A.</i>	Date 31-03-08	Variation N° 256/08
		Responsable <i>Neri Maria</i>	Date 31-03-08	Date 31-03-08
Description MEDICAL PAPER HL 60g (Material Sheet)				
Code 2501000000		Rev. D	Pag. <u> 1 </u> of <u> 1 </u>	

OMN



10.06.2015 - Annex 4



ANNEX 4

STERILIZATION PROCESS VALIDATION

The sterilizable KaVo hose set is comparable, for components, intended use and mode of use to the sterilizable line used for sterilization process validation, which defines:

1. Sterilisation of the line at 121 ° C by steam (autoclave tipoB)
2. Re-sterilizable for a maximum of 25 times
3. Method of reconditioning of the line after each use

The reports show that the line does not alter the components and functionality as a result of the 25 cycles, as it is not altered the functionality.

These are the standards applicable for protocol validation:

- European Pharmacopoeia – current ed.
- UNI EN ISO 11737-1:2006 → Sterilization of medical devices – Microbiological methods – Part 1: Determination of population of microorganisms on products
- UNI EN ISO 11737-2:2010 → Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- UNI EN ISO 11138-1:2006 → Sterilization of health care products – Biological indicators – Part 1: General
- UNI EN ISO 11138-3:2009 → Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization process

Report 14/2011 – 08/08/2011 → Validation of steam sterilization

Report 39/2012 – 27/07/2012 → Technical assessment

Report 40/2012 – 27/07/2012 → Evaluation of toxicity

For each production, we carry out the bioburden analysis in order to define and monitor the level of contamination, in accordance with the limits identified in the validation of the sterilization process.

Specifically, on the KaVo hose set, tests were conducted to evaluate the re-sterilization of the seal assembly of the component 1 with component 20 using the silicone tube component 23. Functionality tests were performed and confirmed by the customer on the samples provided with lot 15150.