PDS
Product Data Sheets
IRRIGATION LINE - 1.011.0633

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: - 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: - 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

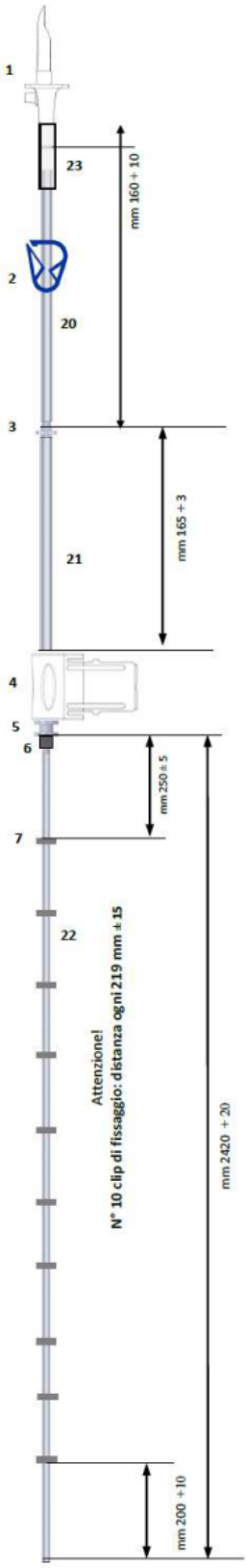
	First packaging	Second packaging	Final packaging	Pallet 120x80
No pcs	1	2	22	880
Box /envelope	Plastic/paper envelope Medical paper 60 gr/m² - Plastic film PET12/PP40 PEEL	White box 25x30x4h cm + N° 1 copy of the IFU	Box 37,5x28x41h cm	/

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*



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

ANNEX 1

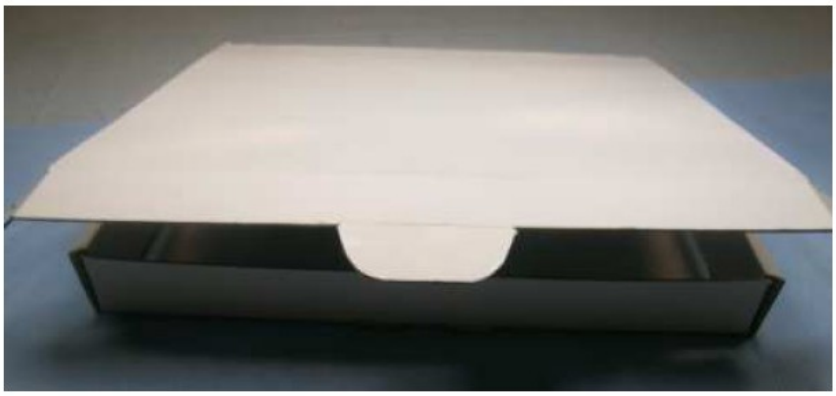
LABELS and IFU

First packaging	Plastic/paper envelope 20 x 30 cm Medical paper 60 gr/m² - Plastic film PET12/PP40 PEEL Label 10 x 15 cm

Barcode construction

	LIC	Ref.	Packaging level		Q.ty field		Lot field		Check digit
BLISTER (1 PC)	+EFID	1.011.0633	0	/$$	8	01	7	<assigned> e.g. **123456**	<calculated> **1**
BOX (2 PCS)			1			02			<calculated> **3**
CARTON (22 PCS)			2			22			<calculated> **6**

Second packaging	Carton box – white - 25x30x4h cm – 2 pc + IFU Label 10 x 15 cm

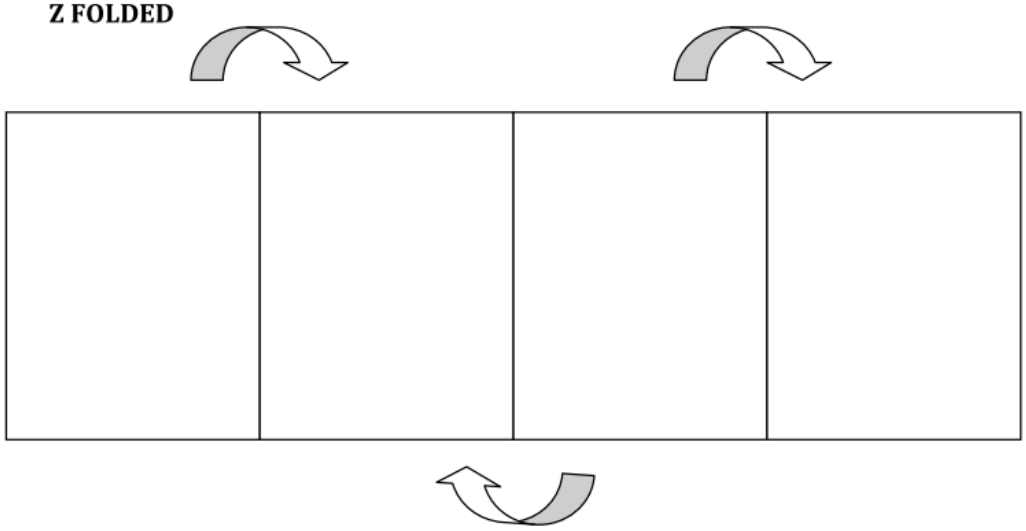


Final packaging	Carton box – white – 37,5x28x41h cm – 22 pc Label 10 x 15 cm

IFU – 80.M0050 – REV00/APRILE/2015

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

Z FOLDED



ПРИГОДНЫЙ ДЛЯ СТЕРИЛИЗАЦИИ КОМПЛЕКТ ШЛАНГОВ S600

REF. 1.011.0633

STERILISABLE HOSE SET S600
for the dental,oral and orthodontic area

LINEA DI IRRIGAZIONE STERILIZZABILE S600
per uso odontoiatrico e maxillo facciale

STERILISIERBARES SCHLAUCHSET S600
für den Zahn- / Mund- und Kieferbereich

JUEGO DE MANGUERAS ESTERILIZABLES S600
para el área dental, bucal y maxilar

ПРИГОДНЫЙ ДЛЯ СТЕРИЛИЗАЦИИ КОМПЛЕКТ ШЛАНГОВ S60
для использования в стоматологии, ортопедии и челюстной медицине.

歯・口内・顎域用滅菌チューブセットS600。

软管套装 S600（可消毒）用于牙科/口腔和颌骨领域。

Manufacturer OMNIA Spa 43036 Fidenza (PR) - Italy www.omniapa.eu

CE 0546

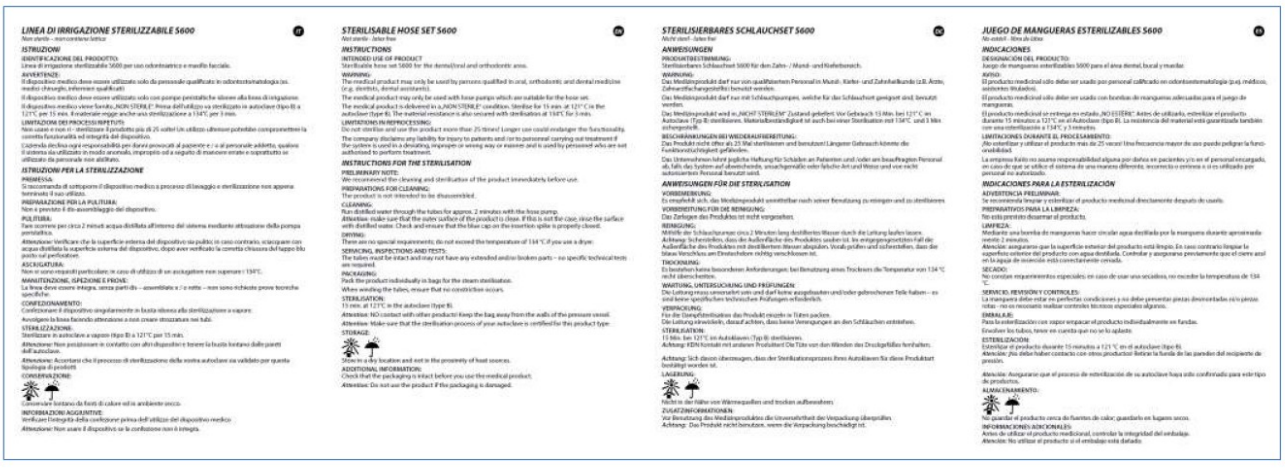
Consult instruction for use

Do not use if package is damaged

Not made with natural rubber latex. PHTHALATE FREE

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

10.06.2015 – Annex 1



LINEA DI IRRIGAZIONE STERILIZZABILE S600

STERILISABLE HOSE SET S600

STERILISIERBARES SCHLAUCHSET S600

JUEGO DE MANGUERAS ESTERILIZABLES S600

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/dm³
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 expasion	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 ☐
: Moulding ☒
: Blowing ☐

PACKAGING : Goods delivered in polythylene or paper bags weighing 25 kg each or 600-800 kg

ASPECT : Plastic granules
Colourless ☒
Red ☐
Blue ☐
White ☐
_____ ☐

STORAGE CONDITIONS : Maintain cointainers closed in a clean and well-aired environment
Avoid direct light and excessive humidity.

STERILIZATION TYPE :
Ethylene oxide ☒
Gamma radiation ☐
Steam ☒

NOTES : -This material can be used for components which come into contact with blood and/or "solutions".

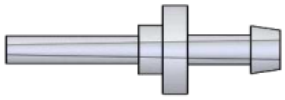
COMPONENT 2: CLAMP —PP

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

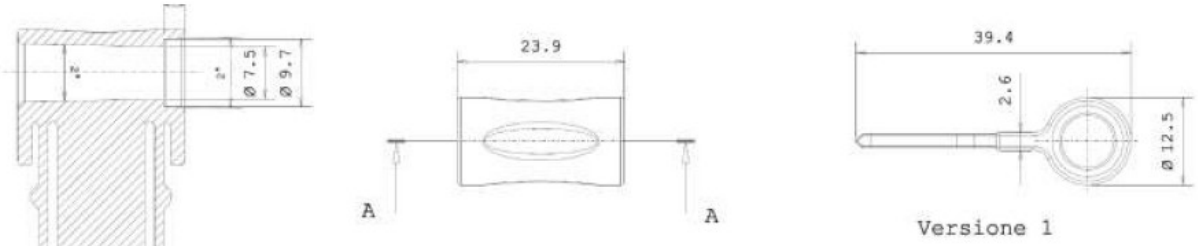


KOCETAL® K300

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	ASTM D648		
HDT/A 0.45 MPa (4.6 kg/cm^2)		°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	$\times 10^{-5}$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	$\times 10^{16}$ Ω	1
Volume Resistivity	ASTM D257	$\times 10^{14}$ Ω·cm	1
Dielectric Strength	ASTM D149	kV/mm	19
Dielectric Constant	ASTM D150	-	3.7
Dielectric Dissiparation 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 name(s) : 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 & Suppher's stamp

COMPONENT 5 : CONNECTOR

Bayer MaterialScience

Apec 1745

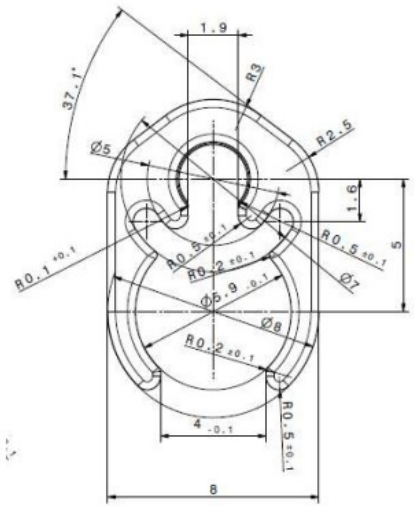
Standard grades / Medical applications, suitable for superheated steam sterilization

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	Metodo		Nostra Mescola
Peso specifico	UNI 7092-A	g/cm3	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. 25% 175°C 22h.	UNI 4913/A	%	30 max

Resistenze chimiche e fisiche

Resistenza a :

IMPERMEABILITA' AI GAS	Insufficiente
ARIA CALDA FINO A 180°C	Ottima
AGENTI ATMOSFERICI	Ottima
OZONO	Ottima
IRRIGIDIMENTO BASSA TEMPERATURA	Ottima
OLII MINERALI PARAFFINICI	Buona
IDROCARBURI ALIFATICI	Insufficiente
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 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		Nostra Mescola		Valori Richiesti
Peso specifico	UNI ISO 1183-1	g/cm³	1,140 +/-	0,020	
Durezza	UNI EN ISO 868	SHORE A	50,000 +/-	5,000	
Carico di Rottura	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		
Compressione 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 sor ricavate sia dalle caratteristiche intrinseche dell'elastomero di base, sia dalla natura chimica degli altri ingredie ti presenti nella mescola con la quale è prodotto il manufatto. Comunque, i dati vengono comunicati a titolo informat vo e non impegnano la società POSA SPA

Temperatura d'Impiego : Min - 60°C Max 180°C

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/cm³
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/m³
COF	ASTM D1894	0,15 ÷ 0,30	/
Point/fusion interval	/	150 ÷ 170	°C
ADHESIVE			
Weight	/	1,6 ÷ 2	g/m²

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.

CONFORMITY TO STANDARD

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.

Conformity of the components to Standards applied:

PET POLYETYLENE – UE: Commission Directive 2002/72/CE, 2004/19/CE, 2005/79/CE, 94/62/CE, 2002/16/CE, 2007/19/CE, Regolation 683/98, 1935/2004 and 1895/2005; Italy: Ministerial Decress 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

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 1, part B; USA: FDA, CFR, title 21 (2002) § 177.1520 (a) (1), (b) and (c) 1.1

ADHESIVE – UE: Commission Directive 2002/72/CE; Italy: Ministerial Decrees 21.3.1973; USA – FDA, CFR, title 21 § 175.105

DESCRIPTION MATERIAL

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.

APPLICATION

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 *Steam* and EO (gas) sterilization.

TRACEABILITY

The product/raw material is guaranteed through documentations keep by QC Encaplast's files for a period of 10 years.

GENERAL CONDITIONS OF STORAGE

15-25°C 60% UR

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.

ENCAPLAST®

Drawer	Date	Variation N°
Marchi A.	31-03-08	256/08
Responsable	Date	Date
Neri Mario	31-03-08	31-03-08

Description

Composite Film PET 12 / PP 40 Green (Data Sheet)

Code	Rev.	
2503350000	C	Pag. 1 of 1

OMN

PROPERTY PHYSICAL-CHEMICAL	Standards	Tipical Value	Unit of Measure
Paper Grammage	ISO 536	60	g/m²
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/m²
Hydrophobia (water repellency)	ASTM D779-03	35	sec
Fluorescence	DIN 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 (BgVV) 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 hight bacterial barrier. Is indicated as a support for flex graphic and rotogravure printing.

APPLICATION

Medical Paper HL 60g/m² is expecially indicated for the production of pouches and rolls, printing and unprinting, where the Paper is hot welding with composit 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 I Medical Device Directives 93/42/CEE, since product supplied by Encaplast is considered a component of the Medical Device.

ENCAPLAST®

Drawer	Date	Variation N°
Marchi A.	31-03-08	256/08
Responsable	**Date**	**Date**
Neri Mario	31-03-08	31-03-08

Description: MEDICAL PAPER HL 60g (Material Sheet)

Code	Rev.	Pag. 1 of 1
2501000000	D	

OMN

ANNEX 4

STERILIZATION PROCESS VALIDATION

The sterilizable KaVo hose set is is comparable, for components, intended use and mode of use to the sterilizable line used for steriization 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 manteinance 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.